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Animal and Plant Health Inspection Service

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Regulatory Impact Analysis & Initial Regulatory Flexibility Analysis

Proposed Rule

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Importation, Interstate Movement, and Environmental Release of Organisms Produced through Genetic Engineering (7 CFR part 340)

Policy & Program Development

Policy Analysis & Development

Summary

Under the Plant Protection Act (PPA, 7 USC 7701-7772), the Secretary of Agriculture is authorized to regulate the movement into and through the United States of plants, plant products, and other articles to prevent the introduction or dissemination of plant pests and noxious weeds. As one part of its implementation of the PPA, APHIS regulates the safe introduction (environmental release, interstate movement, and importation) of certain genetically engineered (GE) organisms that might be plant pests (7 CFR part 340). APHIS is proposing to revise its regulation of GE organisms to respond to emerging trends in genetic engineering, to more efficiently use APHIS resources, and eliminate unnecessary regulatory burdens.

The proposed revisions to 7 CFR part 340 would create the framework for more focused, risk-based regulation of the GE organisms that pose plant pest and/or noxious weed risks. They would establish a regulatory status evaluation process in which risk analysis would be used to assess whether permitting of a GE organism is necessary. Shipping standards would be less prescriptive and more generally applicable, and the rule would provide for the issuance of multi-year permits. The proposed rule would also exclude certain techniques from the definition of genetic engineering and certain organisms from the definition of genetically engineered organism. These changes would improve the efficiency and clarity of the regulations.

The proposed amendments would benefit developers, producers, and consumers of certain GE organisms, public and private research entities, and the Agency. There would not be any decrease in the level of protection provided against plant pest risks and protection against noxious weed risks would be enhanced. The risk-based process used to determine regulatory

status under the proposed rule would provide cost savings to the biotech industry and allow for reallocation of APHIS resources to Biotechnology Regulatory Services (BRS) priorities.

Based on APHIS' experience evaluating field trial data from thousands of permits that authorize environmental release of regulated organisms, as well as more than 150 petitions for non-regulated status, APHIS has determined that most of the GE organisms evaluated by the Agency do not merit regulatory oversight under the PPA. There would be both direct and indirect economic benefits of not subjecting the majority of these organisms to permitting requirements.

Direct regulatory costs to biotech developers would be reduced for those organisms that are not considered to pose plant pest and/or noxious weed risk. Savings to the regulated community would result from a reduced need to collect field data, fewer reporting requirements, and lower management costs. Petitions for non-regulated status—and the petition costs incurred—would be eliminated. There would be some new costs borne by regulated entities under the proposed rule including rule familiarization and recordkeeping. Recordkeeping cost tabulations are based on the information collection categories from the paperwork burden section of the rule, and are estimated to total about $275,000. About 1,100 distinct entities have applied for permits or notifications under part 340. APHIS estimates that those entities would spend about 8 hours becoming familiar with the provisions of this rule at a total cost of about $576,000.

Cost savings for these entities are expected to more than offset the new costs. APHIS estimated the cost savings for two regulatory oversight scenarios, based on a study of the costs encountered by private biotech developers as they pursue regulatory authorization of their innovations. When only USDA has regulatory oversight, compliance cost savings under the proposed rule could range from $1.5 million to $5.4 million for the development of a given GE

trait. If EPA and/or FDA also have an oversight role in the development of a given GE trait, compliance cost savings could range from $485,000 to $861,000. Since 1992, between 2 and 14 petitions have been processed (granted non-regulated status or the petition withdrawn) in a given year, with an average of just under 6.

Because the rule is expected to spur innovation, we expect the number of new organisms developed annually to increase over time. In the following discussion, we assume the annual number of new GE organisms developed under the proposed rule would range from 6 (the current annual average) to 12 (twice this average), with 10 as an intermediate number. For GE organisms that would have solely required USDA oversight, the annual savings could range from $8.8 million to $32.4 million (6 new organisms), from $14.7 million to $53.9 million (10 new organisms), and from $17.6 million to $64.7 million (12 new organisms). For organisms that are submitted for multi-agency evaluation, the annual savings could range from $2.9 million to $5.2 million (6 new organisms), from $4.9 million to $8.6 million (10 new organisms), and from $5.8 million to $10.3 million (12 new organisms).

APHIS costs of regulating GE organisms that may pose plant pest or noxious weed risks also are expected to change under the proposed rule. Fewer permits would be issued and notifications and petitions for non-regulated status would be eliminated, but more risk assessments for regulatory determination would be performed. Current annual personnel costs of conducting GE activities (costs of activities that would be affected by the proposed rule) are estimated to total about $5.6 million. With the proposed rule, annual costs are expected to range from $2.5 million to $7.8 million, depending on the volume of permits, weed risk assessments, inspections, and NEPA activities. In addition, costs to APHIS of implementing the proposed rule would include outreach activities, developing guidance documents, training, and adjusting

the current permit system. APHIS estimates that the public outreach, guidance and training would cost about $88,000. Requests for regulatory status and response letters under the proposed rule could be handled in a manner similar to the current 'Am I Regulated' process outside the electronic permitting system without incurring new costs.

A quicker USDA evaluation process and related reduction to firms' regulatory uncertainty may facilitate small companies' ability to raise venture capital. Reduced regulatory requirements may also lead to greater participation by the public sector in GE research. These indirect benefits of the proposed rule may spur GE innovations, particularly in small acreage crops where genetic engineering has not been widely utilized due to the expense of regulation.

While the proposed rule may help promote biotech innovations, the pace of commercialization and volume of GE products commercialized are not expected to change dramatically from current levels. Nor is control over the development process expected to be materially altered by the proposed rule. It would be in a biotech developer's own best interest to maintain the same level of supervision and control over the development process as at present to prevent undesired cross-pollination or commingling with non-GE crops.

GE crop varieties, in general, are not required to be reviewed or approved for safety by the FDA before going to market. However, the developer is responsible for ensuring product safety and developers consider voluntary consultations with FDA on food safety to be an absolute necessity for applicable GE products.[1] Developers also have various legal, quality control and marketing motivations to maintain rigorous voluntary stewardship measures. APHIS

[1] Genetically Engineered Crops: Past Experience and Future Prospects. Committee on Genetically Engineered Crops: Past Experience and Future Prospects; Board on Agriculture and Natural Resources; Division on Earth and Life Studies; National Academies of Sciences, Engineering, and Medicine.

therefore believes that developers would continue to utilize such measures for field testing even in cases where USDA would not require a permit.

Certain plants are genetically engineered in order to produce pharmaceutical or industrial compounds (plant-made pharmaceuticals or industrials, or PMPIs). Under the provisions of the proposed rule, there is a possibility that APHIS could reach a determination that a GE plant that produces PMPIs is not a regulated organism. Such a plant would not be subject to field trial oversight by USDA, and could be planted before or without an evaluation by FDA or EPA. Several options have been identified for addressing this potential gap in oversight. APHIS estimates that current PMPI inspections cost roughly $35,000 in total annually or about $800 each on average. Assuming that oversight continues in the same manner as APHIS oversight, a similar government expenditure could be expected under any of the PMPI oversight scenarios.

Certain plants are genetically engineered to produce plant-incorporated protectants (PIPs). PIPs fall under the regulatory oversight of EPA. However, APHIS exercises regulatory oversight of all PIP plantings on 10 acres or less of land. Under the proposed rule, APHIS would only require permits for PIPs planted on 10 acres or less if they present a plant pest or noxious weed risk or have not yet been evaluated by APHIS for such risk. This proposal would shift Federal oversight of small-scale (10 acres or less) outdoor plantings of PIPs to EPA. EPA may decide to require EUPs for all, some, or none of such PIPs, and may conduct inspections of all, some, or none of those PIPs under permit. EPA would need to develop a program to oversee small-scale testing of PIPs and issue regulations if warranted. APHIS is fully committed to coordinating with EPA in this matter in order to give EPA time to stand up such a program. APHIS understands that a memorandum of understanding (MOU) and services agreement may be necessary to provide personnel and other resources to assist EPA during the interim period

while EPA implements its own program of oversight of outdoor planting of PIPs on 10 acres or less. APHIS recognizes that there are challenges associated with such a transition that also would require EPA to incur the costs associated with setting up a revised regulatory program. Further, it would require policies, procedures, and guidance regarding APHIS' interaction with EPA.

Farmers who adopt GE crops also may indirectly benefit from the proposed rule. The adoption of GE crops in the United States has generally reduced costs and improved profitability at the farm level. As mentioned, under the proposed rule, regulatory costs are expected to be lower, thereby potentially spurring developer innovation, especially among small companies and universities. Farmers may benefit by having access to a wider variety of traits as well as a greater number of new GE crop species, affording them a broader selection of crops to suit their particular management needs. Among the types of innovations expected are crops with greater resistance to disease and insect pests, greater tolerance of stress conditions such as drought, high temperature, low temperature, and salt, and more efficient use of fertilizer. These types of traits can lower farmer input costs (water, fertilizer, pesticide) and increase yields during times of adverse growing conditions.

On the other hand, some farmers (e.g., growers of organic and or identity-preserved crops) could be negatively impacted by these same innovations. Some consumers choose not to purchase products derived from GE crops and instead purchase commodities such as those labeled "non-GMO" or organic. When crops intended for the non-GE or identity-preserved marketplace contain unintended GE products, the value of the non-GE or identity-preserved product is diminished. Effects of the proposed rule on the variety of GE crop species grown in the United States and their wider adoption may increase risks of cross-pollination or

commingling. As more small acreage crops are modified using genetic engineering, the unintended presence of a GE organism becomes increasingly possible. Unauthorized releases of regulated GE crop plants and the entry of regulated plant material in the commercial food and feed supply can have impacts on domestic or international markets. While such releases have occurred and may occur again, such incidents are expected to be rare.

Entities potentially affected by the proposed rule fall under various categories of the North American Industry Classification System. While economic data are not available on business size for some entities, based on industry data obtained from the Economic Census and the Census of Agriculture we can assume that the majority of the businesses affected by the proposed rule would be small. APHIS welcomes public comment on the proposed rule's possible impacts.

The following table provides a summary statement of the expected direct benefits and costs of the proposed rule:

Expected Annual Benefits and Costs of the Proposed Rule for the Biotechnology Industry and for USDA, 2015 dollars

Entity			
Biotechnology Industry	Costs ($1,000)		
Developer costs (recordkeeping and rule familiarization)[1]	851		
	Cost Savings ***per Trait*** ($1,000)		
Developer Savings [2]		Proposed Rule, lower bound	Proposed Rule, upper bound
USDA sole regulatory agency		-1,468	-5,393
USDA with FDA and/or EPA oversight		-485	-861
APHIS Biotechnology Regulatory Services	Costs ($1,000)		
Costs for public outreach, training, and epermitting[3]	88		
Activities affected by the rule	Current Rule	Proposed Rule, lower bound	Proposed Rule, upper bound
Notifications	203	0	0
Petitions	2,130	0	0
Interstate movement and environmental release permits	239	139	261
Courtesy permits	19	0	0
Letters of No Permit Required	0	3	3
“Am I Regulated” Process	7	0	0
Weed risk assessments	0	700	1,265
Compliance and Inspections	361	361	1,014
NEPA/ESA	2,648	1,324	5,297
TOTAL[4]	**5,607**	**2,527**	**7,840**

[1] Becoming familiar with the rule are one-time costs.

[2] These savings are shown on a per trait basis. If between 6 and 12 GE organisms are developed each year that would have solely required USDA oversight, annual savings could range from $9 million to $64.8 million. If between 6 and 12 new GE organisms per year are submitted for multi-agency evaluation, the annual savings could be from $2.9 million to $10.3 million.

[3] Requests for regulatory status and response letters under the proposed rule could be handled in a manner similar to the current 'Am I Regulated' process outside the electronic permitting system without incurring new costs.

[4] Annual staffing costs of APHIS Biotechnology Regulatory Services total about $19 million.

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Introduction

Under the Plant Protection Act (PPA, 7 USC 7701-7772), the Secretary of Agriculture is authorized to regulate the movement into and through the United States of plants, plant products, and other articles to prevent the introduction or dissemination of plant pests and noxious weeds. As one part of its implementation of the PPA, USDA's Animal and Plant Health Inspection Service (APHIS) regulates the safe introduction (environmental release, interstate movement, and importation) of certain GE organisms that might be plant pests, as set forth in 7 CFR part 340. APHIS is proposing to revise 7 CFR part 340 in order to incorporate additional authorities provided by the Plant Protection Act. The revisions would also update the regulations in response to advances in genetic engineering and our accumulated experience regulating GE organisms. This proposed rule would be the first comprehensive revision of the regulations since they were established in 1987.

We are proposing the following revisions to 7 CFR part 340:

- Incorporate the noxious weed authority from the PPA, specifically for GE organisms.
- Describe regulatory scope related to organisms developed using genetic engineering (GE organisms).
    - Genetic engineering. Techniques that use recombinant or synthetic nucleic acids with the intent to create or modify a genome. APHIS considers synthetic nucleic acids to be nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules. For the purposes of the regulations, this definition does not include traditional breeding (including marker-assisted breeding as well as

tissue culture and protoplast, cell, or embryo fusion) or chemical or radiation-based mutagenesis.

- GE organism. An organism developed using genetic engineering. Organisms are not considered a GE organism if:
    - The genetic modification to the organism is solely a deletion or single base pair substitution which could otherwise be obtained through the use of chemical- or radiation-based mutagenesis; or
    - The genetic modification to the organism is solely introducing only naturally occurring nucleic acid sequences from a sexually compatible relative that could otherwise cross with the recipient organism and produce viable progeny through traditional breeding (including, but not limited to, marker-assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion); or
    - The organism is a "null segregant," that is, the progeny of a GE organism where the only genetic modification was the insertion of donor nucleic acid into the recipient's genome, but the donor nucleic acid is not passed to the recipient organism's progeny and the donor nucleic acid has not altered the DNA sequence of the progeny.

- Eliminate the phrase 'regulated article' from the regulations and replace it with a new phrase, 'regulated organism,' defined under Sec. 340.0 of the proposed rule.
- Eliminate the current notification procedure. Importation, interstate movement or release into the environment of regulated GE organisms would be authorized under a permit with specific conditions.
- Implement a new regulatory framework that would assess plant pest and/or noxious

weed risks and determine whether a GE organism merits regulation by permitting.

- APHIS would regulate a GE organism that is intended for use as a biological control (bio-control) agent if APHIS determines that it is a plant pest or noxious weed, or the organism has not been evaluated by APHIS for plant pest or noxious weed risk, with limited exceptions discussed in the preamble.
- GE plants engineered to produce pharmaceutical and industrial compounds (plant made pharmaceuticals and industrials (PMPIs) would not be regulated organisms under 7 CFR part 340 unless they pose a plant pest and noxious weed risk. Under the provisions of the proposed rule, there is a possibility that APHIS could reach a determination that a GE plant that produces PMPIs is not a regulated organism, without field trials first being conducted. Without the precautions and safeguards that APHIS requires for permitted, outdoor plantings of plants that make PMPIs, there is an increased likelihood of plants that produce PMPIs being inadvertently introduced into the food or feed supply before or without evaluation by FDA or EPA. Several options have been identified for addressing this potential gap in oversight and are discussed below.
- Replacement of courtesy permits and accompanying Letters of No Jurisdiction (BRS-issued permits for non-regulated GE organisms, to facilitate movement) by Letters of No Permit Required; permits would only be issued for regulated organisms.
- Clarify actions the Administrator may take with respect to compliance, enforcement, or the need for remedial actions as authorized in the PPA. Make explicit APHIS' authority to amend, transfer, deny, or revoke a permit or permit conditions.
- Eliminate prescribed shipping container provisions in favor of general conditions

applicable to all shipments, with additional, shipment-specific conditions specified on permits themselves.

- Change existing records requirements to ensure that APHIS has sufficient information to monitor compliance with its regulations and maintain effective oversight of regulated organisms, in accordance with provisions of The Food, Conservation, and Energy Act of 2008 (Farm Bill) and recommendations from the OIG in its reports "Controls Over Issuance Of Genetically Engineered Organism Release Permits," Audit Report 50601-8-Te, December 2005, and "Office of the Inspector General: Controls Over APHIS' Introduction of Genetically Engineered Organisms," Audit Report 50601-001-32, September 2015.

This document provides a benefit-cost analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This document also examines the potential economic effects of the rule on small entities, as required by the Regulatory Flexibility Act.

Background

Agricultural Genetic Engineering

Agricultural genetic engineering uses a range of tools, including traditional breeding techniques that alter living organisms, or parts of organisms, to make or modify products; improve plants or animals; or develop microorganisms for specific agricultural uses.

Traditional genetic engineering uses cross- and selective-breeding methods to develop new varieties with specific desirable characteristics. Selective breeding involves choosing traits with desired characteristics and propagating them repeatedly over several generations. Because the genes that contribute special characteristics are not explicitly identified in most cases, the desired characteristic is usually achieved through time-consuming trial and error. The most notable limitation of this method is that two species can only be cross-bred if they are closely related (Subramaniam and Reed 2015). Traditional breeding also uses chemical and radiation mutagenesis to introduce variation that increases the desirable characteristics that can be selected. Thousands of varieties have been created using mutagenesis and these varieties are not excluded from use in organic and non-GE production systems (Joint FAO/IAEA Mutant Variety Database https://mvd.iaea.org/; 7 CFR part 205.2).

Modern gene technologies in conjunction with deeper understanding of gene function allow scientists to identify specific genes associated with desirable characteristics and create valuable new phenotypes in GE organisms. These technologies accelerated development of new transgenic products in many fields, including the pharmaceutical, manufacturing, and agricultural sectors. In the agricultural sector, plants have been developed that are resistant to pests and disease, fruits and vegetables developed with increased shelf life, plants developed

with increased productivity, and plants developed with altered nutritive values, among other characteristics (Subramaniam and Reed 2015).

It has been 20 years since GE varieties with pest management traits first became commercially available for major crops in the United States. In 2013, approximately 169 million acres of GE corn, soybeans, and cotton were planted, accounting for approximately half of the land used to grow all U.S. crops (Fernandez-Cornejo et al. 2014). Planting of GE crops increased by 68 percent between 2000 and 2005, and by another 45 percent between 2005 and 2013.

On a global scale, approximately 420 million acres of GE crops were planted in 28 countries in 2012 (International Service for the Acquisition of Agri-biotech Applications 2012). U.S. acreage accounted for approximately 41 percent of the planted area; Brazil, 21 percent; Argentina, 14 percent; Canada, 7 percent; India, 6 percent; and China, Paraguay, South Africa, and Pakistan, each roughly 2 percent.

U.S. Regulation of Agricultural Genetic Engineering

The Federal government has a coordinated, risk-based system to ensure that new GE organisms and/or products are safe for the environment and human and animal health. Established as a formal policy in 1986, the Coordinated Framework for Regulation of Biotechnology describes the policy of the federal agencies involved with the review of GE products. The Coordinated Framework is based upon existing laws designed to protect public health and the environment. Under the Coordinated Framework, Federal regulatory policy to ensure the safety of GE products is carried out by the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture (USDA). Products are regulated according to their nature, characteristics, and application, with some products being regulated by more than one agency.

The EPA uses a registration process to regulate the sale, distribution, and use of pesticides in order to protect health and the environment, regardless of how the pesticide was made or its mode of action. This includes regulation of pesticides produced by an organism through genetic engineering. The FDA is responsible for ensuring the safety and proper labeling of human and animal food, including those produced using genetic engineering. Additional FDA labeling of foods containing GE ingredients is only required when such foods have nutritional or functional characteristics that are materially different from their conventional counterparts. Under new legislation, which amended the Agricultural Marketing Act, USDA will now regulate the disclosure of GE ingredients in foods regardless of whether the presence of such ingredients causes a material change in the resulting food product. FDA encourages developers of new plant varieties to participate in its voluntary consultation process to ensure that human and animal food safety and related regulatory issues for a new plant variety are resolved prior to commercial distribution.

USDA APHIS is responsible for protecting U.S. agriculture against threats from pests and diseases. The Secretary of Agriculture's authority under the PPA to restrict importation, interstate movement, and release into the environment of plants, plant products, biological control organisms, noxious weeds, or other articles when necessary, to prevent the dissemination of plant pests or noxious weeds, includes GE organisms that may pose a risk as a plant pest or noxious weed.

APHIS regulates the introduction of GE organisms as set forth in 7 CFR 340. Under the current regulations, APHIS determines whether to authorize the introduction of GE organisms through either permit or notification procedures (collectively known as "authorizations") based on whether the item will pose a plant pest risk to the environment or agriculture. For both

notifications and permits, applicants provide information on the organism, the proposed activity, and the proposed starting dates of the activity. The notification procedure is an administratively streamlined alternative to the permitting process for certain GE plants. The GE plant must meet specified eligibility criteria and the introduction must meet certain performance standards described in the regulation. APHIS reviews notifications to verify that the GE plants meet the eligibility criteria and also evaluates whether the proposed introduction can be done in a manner that meets the performance standards. These performance standards include, among other things, that, when the regulated article is to be used for environmental release, it must be planted in such a way that it is not inadvertently mixed with non-regulated plant material that is not part of the environmental release. In addition, the environmental release must be conducted such that the regulated article will not persist in the environment, and no offspring can be produced that could persist in the environment.

APHIS also authorizes introductions under permits that include specific, customized conditions that must be followed by the permit holder. Such conditions include, but are not limited to, maintenance of the regulated article's identity through labeling, retention of records related to the article's specified use, segregation of the regulated article from other organisms, inspection of a site or facility where regulated articles are to undergo environmental release or will be contained after their interstate movement or importation, and the maintenance and disposal of the regulated article and all packing material, shipping containers, and any other material accompanying the regulated article to prevent the dissemination and establishment of plant pests. APHIS conducts inspections of authorized permits and notifications, ensuring the permit conditions are being followed and performance standards are being met.

APHIS regulates certain GE organisms that are known or suspected to be plant pests or to pose a plant pest risk. These are called "regulated articles." APHIS regulates the import, interstate movement, and release into the environment of regulated organisms, including organisms undergoing confined experimental use or field trials. Importation, interstate movement, and environmental release of regulated articles are reviewed to ensure that, under the proposed conditions of use, they are unlikely to present a plant pest risk

A researcher or developer may also request that APHIS no longer regulate an organism by submitting a petition for non-regulated status, which allows the planting and movement of a GE organism without a permit. The petitioner must supply information, described in 7 CFR 340.6, such as the biology of the recipient plant, experimental data and publications, genotypic and phenotypic descriptions of the GE organism, and field test reports.

Environmental Releases

From 1987 through 2015, APHIS authorized more than 18,400 environmental releases, that is, over 94 percent of the nearly 19,500 applications received (table 1). These release authorizations allowed plantings at more than 125,000 sites. The majority of the applications approved for environmental release were for corn (8,225), followed by soybeans (2,430), cotton (1,159), potatoes (944), tomatoes (709), and wheat (523). The number of field release authorizations issued by APHIS for GE organisms increased from 5 in 1987 to 1,191 in 2002, and has averaged around 750 per year since. In terms of GE traits, the majority of the applications approved are for herbicide tolerance (7,534), followed by agronomic properties

such as drought resistance (6,777), product quality (5,434), insect resistance (5,267), "other" traits (2,564), marker gene (2,406), virus resistance (1,452), and fungal resistance (1,448).[2]

A permit or notification can include many sites and authorize many different phenotypic designations[3] to be tested at each site. Thus, while the number of APHIS notifications and permits peaked in 2002, a more accurate indicator of the increase in research and development activity involving GE products is the number of authorized sites, acres, and phenotypic designations approved in a given year. For instance, while the number of crop releases authorized in 2015 was only about half the number in 2006, the number of sites authorized in FY 2015 was about double the number authorized in 2006, the number of acres was almost 5.5 times larger, and the number of authorized phenotypic designations was 21.5 times larger (table 1).

[2] Compiled from Virginia State and Polytechnic University data: http://www.isb.vt.edu/search.aspx?CommandName=search&searchterm=environmental+releases&sort=relevance

[3] A phenotypic designation or gene construct is the functional unit necessary for the transfer or the expression of a gene of interest. Apart from the gene of interest, itself, a so-called promoter ("starter") and a terminator ("stop signal") are required for expression. In most cases, additional sequences are included, e.g. marker genes, which are also accompanied by a promoter and a terminator. The name "construct" is used because the sequences normally do not exist in this combination, but must be "put together". (http://www.gmo-safety.eu/glossary.html)

Table 1: Number of Releases, Sites, Acres and Phenotypic Designations authorized by APHIS, 1987-2015

Year	Releases	Release Sites [1]	Acres [1]	Phenotypic Designations
1987	11	---	---	5
1988	16	---	---	16
1989	30	---	---	30
1990	51	---	---	50
1991	90	---	---	89
1992	160	---	---	160
1993	301	508	948	306
1994	579	1,731	8,117	585
1995	711	3,683	62,394	710
1996	612	2,742	7,084	604
1997	763	3,474	23,817	761
1998	1,071	5,099	89,620	1,075
1999	983	3,973	56,959	1,005
2000	925	3,708	40,199	904
2001	1,083	5,765	54,195	1,083
2002	1,194	5,130	139,023	1,191
2003	813	2,976	24,713	810
2004	893	4,421	58,809	891
2005	955	4,961	99,510	956
2006	865	4,256	84,061	2,149
2007	932	3,605	45,931	4,920
2008	871	7,878	182,964	8,581
2009	751	6,724	166,315	16,650
2010	660	6,683	139,517	30,770
2011	792	10,384	235,226	35,186
2012	665	8,652	374,338	38,795
2013	602	10,725	368,384	50,963
2014	557	10,561	365,089	39,382
2015	467	8,274	447,631	46,214

[1] Records of the release sites and authorized planting acreages prior to 1993 are not complete and are not included here.

Importation and Interstate Movements

APHIS regulates the movement into and through the United States of plants, plant products, and other articles to prevent the introduction or dissemination of plant pests and

noxious weeds. In 2015, there were 39 import permits and 104 interstate movement permits issued for GE organisms. There were also 97 import notifications, 325 interstate movement notifications, and 232 combination interstate movement and release notifications for GE organisms acknowledged in 2015.

Overview of the Action

Consistent with the authorities in the PPA, APHIS' goal under 7 CFR 340 is to regulate GE organisms that pose plant pest and/or noxious weed risk. Currently, APHIS requires issuance of a permit or a notification procedure for importation, interstate movement, or outdoor release for organisms that trigger regulation under 7 CFR 340. A developer can petition APHIS to grant non-regulated status for a particular GE organism and, as of November 2016, APHIS has granted such status for GE plants 124 times since the inception of the program. Only after proceeding through the petition process can GE organisms that fall under the regulation be moved or grown in the environment without permit or notification. Many of these GE plants have been commercialized and are available to U.S. growers. APHIS determination of non-regulated status applies to the GE plant as well as its progeny; the GE plant can be used in plant breeding programs and in agriculture without further oversight from USDA.

The proposed rule would streamline APHIS' GE regulatory process by establishing a regulatory status review process in which risk analysis would be used to evaluate whether a permit is necessary for a GE organism to prevent the unauthorized release or dissemination of a plant pest or noxious weed. APHIS would require a permit for importation, interstate movement, or environmental release of organisms that APHIS has determined to present plant pest or noxious weed risks, as well as organisms of potential risk that it has not yet evaluated. Those organisms that are unlikely to pose a plant pest or noxious weed risk would be maintained on a

separate list and would not need a permit for importation, interstate movement, and environmental release. The proposed rule would not result in a decrease in the level of protection provided against plant pest risks, and protection against noxious weed risks would be enhanced by incorporating the noxious weed provision of the PPA into 7 CFR 340.

The proposed rule would eliminate the notification process. During the first six years of APHIS' regulation of GE organisms (1987-1992), all field trials of GE plants were authorized through APHIS' permit process. APHIS introduced the notification process in 1993, initially for six crops (corn, soy, cotton, potato, tobacco, tomato). Importation, interstate movement, or environmental release can be authorized through notification by finding that six eligibility requirements have been met (as described in 7 CFR part 340.3b) and six performance standards can be met (as described in 7 CFR part 340.3c).

APHIS favors regulation through permitting rather than notification because the permitting conditions can be more specific. Permitting allows for increased monitoring of the environment and additional reporting during and after plantings to reduce the likelihood of incidents where unauthorized GE organisms persist in the environment. Plants currently eligible for the notification process would most likely not be subject to permitting requirements based on the criteria that would be used to determine regulatory status under the proposed rule.

APHIS issues courtesy permits for items that are not covered under part 340, in order to facilitate the movement of organisms that are outside the scope of these regulations, but whose movement might otherwise be hindered because of their similarity to regulated organisms. While courtesy permits have been useful to show that the shipments in question are not regulated, their continued use has led to widespread misunderstanding by some researchers that a

courtesy permit removes the requirement for applicants to follow all applicable regulations, including the plant pest regulations found in 7 CFR part 330.

The courtesy permit and accompanying Letter of No Jurisdiction would be replaced by a Letter of No Permit Required to remove such misunderstandings. For entities that have previously used courtesy permits, APHIS would collaborate regarding the entities' importation of non-regulated GE organisms, including how to mark them and who to communicate with to facilitate their movement. APHIS resources needed to issue a Letter of No Permit Required would be about the same as currently required to issue a courtesy permit; however, there would be savings realized over time, as described in the following section. A courtesy permit is valid for three years and is country-specific, whereas a Letter of No Permit Required would be valid in perpetuity for imports from any country.

APHIS proposes to eliminate prescribed shipping container provisions in favor of generally applicable requirements, with additional, shipment-specific conditions specified as permitting conditions. This would allow for greater flexibility than the current highly prescriptive approach because the additional requirements could be tailored to the specific organism, action(s) for which the permit was issued, and other conditions. Such an approach would allow for greater flexibility in meeting safeguarding objectives, while maintaining proper identification and containment of GE organisms during shipment.

This revision is expected to yield modest benefits for the regulated community. To a large extent, general, performance-based standards are currently applied for shipments under notification. The current shipping requirements for regulated articles under permit, as specified in §§ 340.7 and 340.8, are onerous and outdated. For example, metal outer containers are rarely if

ever needed. Most permittees request and are granted variances from the prescribed shipping container requirements due to their unique circumstances.

APHIS proposes to change existing records requirements to ensure that APHIS has sufficient information to monitor compliance with its regulations and maintain effective oversight of regulated GE organisms, in accordance with provisions of the Farm Bill and recommendations of the 2015 USDA OIG report on GE organisms. APHIS is proposing to consolidate all compliance and enforcement requirements in 7 CFR part 340 into a new § 340.5. The new section would also clarify what locations and articles may be subject to inspection. These changes should have, at most, a minor impact on permit holders. The clarifications are functionally the same as current inspection requirements.

The consolidated section covering compliance and enforcement would include requirements for the establishment and maintenance of records related to the permit. The records required to be maintained under this proposed rule are necessary for effective enforcement of the proposed regulations. The maintenance and retention of these records should not significantly affect permit holders. While some of the specific records required under this proposal may not have been explicitly required by the current regulations, they are currently required as part of the supplemental permit conditions that accompany an issued permit. These records include reports and notices such as volunteer monitoring reports, pre-planting notices, and flowering notices. These records are integral to the activities under the permit and should already be maintained by the permit holder as a normal part of business operations and therefore readily accessible.

APHIS is also proposing to increase the length of time required for the responsible person's retention of records. Currently, records must be kept by the responsible person for one year. APHIS proposes to require that records indicating that a regulated organism was imported

or moved interstate and reached its intended destination be retained by the responsible person for at least two years after completion of the importation or interstate movement. APHIS also proposes to require that all other records be retained for 10 years following permit expiration unless determined otherwise by the Administrator and indicated in the supplemental permit conditions or other regulatory requirements, such as an Emergency Action Notification (EAN). The Administrator may specify a different record retention period if, for example, a crop has a dormancy period longer than 10 years. This change is not expected to significantly impact permit holders. Functionally, the requirements will not increase the type of records that must be maintained, just how long those records must be kept. In addition, the number of GE organisms requiring permits is expected to decline, reducing any overall impact of the new permit requirements. APHIS does recognize that, in practice, our proposed requirements would require most records associated with permitted activities to be retained 10 years, and that this is a significant duration to retain potentially a substantial number of records pertaining to permit activities. Therefore, the Agency requests specific public comment regarding whether a shorter duration is warranted for certain records pertaining to permit activities, and which activities these may be. Additionally, APHIS requests comment on any alternate means that stakeholders may identify for the Agency to obtain necessary information from developers in the event of an investigation of possible regulatory noncompliance.

Impact on Affected Entities

Expected benefits of the proposed rule include more efficient regulation of entities by APHIS under part 340. By implementing risk-based regulation, this rule would reduce the regulatory burden associated with organisms that are unlikely to pose a plant pest or noxious weed risk, thereby reducing costs for the biotechnology industry and possibly the Agency.

Resources currently used for regulating organisms that are unlikely to pose plant pest risk could be redirected to the oversight of GE organisms that do pose such a risk. By incorporating the noxious weed authority of the PPA, more oversight of noxious weeds risks would be provided. Together with the focused approach, the government would provide greater scrutiny of GE organisms that pose plant pest or noxious weed risks.

Based on APHIS' experience evaluating field trial data from thousands of permits that authorize environmental release of regulated organisms, as well as more than 150 petitions for non-regulated status, APHIS has determined that most of the GE organisms evaluated by the Agency do not merit regulatory oversight under the PPA. There would be both direct and indirect economic benefits of not subjecting the majority of these organisms to permitting requirements. First, direct regulatory costs to biotech developers would be reduced for those organisms that are not considered to pose plant pest and/or noxious weed risk. Second, a reduced regulatory burden and quicker USDA approval may lead to international regulatory approvals occurring more quickly, facilitation of small companies' ability to raise venture capital, and increased participation by the public sector in GE research, thereby spurring innovation.

On the other hand, an increased rate of GE crop innovation may negatively affect growers of organic or other non-GE crops. Some consumers choose to avoid GE commodities by purchasing products such as those labeled "non-GMO" or organically grown. Other buyers are looking for products with specific identity-preserved traits. When these products are found to have unintended GE traits, their value is diminished.

Innovation is expected to increase under this proposed rule. However, neither the pace of commercialization nor volume of GE products commercialized is expected to change

dramatically from current levels; nor is the biotech developer's control over the development process expected to be materially altered as a result of this rule. It would be in a biotech developer's own best interest to maintain the same level of supervision over the development process as at present. APHIS therefore believes that rigorous stewardship measures would continue to be utilized for field testing even in cases where APHIS would not require a permit.

Undesired cross-pollination or commingling:

1) introduces unwanted characteristics and variability that diminishes the value of a seed crop;
2) increases legal exposure from unauthorized use of intellectual property (if another developer's traits are inadvertently incorporated into their lines;
3) increases legal exposure if unapproved events are detected in crops; and
4) introduces the possibility of the loss of intellectual property and/or confidential business information (if a trait were to escape a developer's control).

Breeding lines are routinely subjected to genome analysis to confirm genetic identity. Even after deregulation, seed companies are motivated to adhere to strict stewardship requirements to maintain the integrity of their crops and reduce legal exposure. Best management practices include maintaining appropriate isolation distances from sexually compatible crops; monitoring and removing volunteers in production fields and the local environments; using color tagging and traceability systems for visual identification of GE plants; and using production best practices regarding equipment monitoring, treatment and cleaning procedures for crop production equipment, seed cleaning, storage, shipping container and screenings disposal requirements, grower guidelines, record keeping, inspections, training, and maintaining a continual review and improvement process.[4]

[4] Loberg, G to: United States District Court for the Northern District of California, San Francisco Division. 2010. Declaration of Greg Loberg in Support of Intervenors' Opposition to PL. Permanent Injunction Case no. 08-0000484, Regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. United States District Court for the Northern District of California, San Francisco Division. Case No. 3:08-cv-00484 JSW.

While the aforementioned measures represent the best practices followed by the sugar beet seed industry, similar stewardship measures have been followed in other instances such as the production of GE alfalfa seed and Enogen® corn where as little as 1 seed in 10,000 can affect the characteristics of processed corn.[5] In the case of alfalfa seed production, the National Alfalfa Forage Alliance has implemented a non-regulatory coexistence strategy, based on grower opportunity zones. A locality can focus on either GE alfalfa seed production or alfalfa seed production targeted for GE sensitive markets, depending on whether the growers on 80 percent or more of the alfalfa seed acres choose production of GE or non-GE seed.[6] In the United States, there are currently 6 grower opportunity zones catering to GE sensitive markets and 21 opportunity zones where GE alfalfa is produced.[7]

FDA and EPA have different oversight roles. GE crop varieties are not required to be reviewed or approved for safety before going to market by the FDA. However, the developer is responsible for ensuring product safety. Developers are encouraged to consult with FDA prior to marketing GE crops, and there is an excellent record of compliance with this guidance. Because developers want to ensure the safety of their products before they are commercialized, they consider voluntary consultations with FDA on food safety to be an absolute necessity for applicable GE products.[8] Just as there are outside motivations for voluntary consultations on food safety, developers also have various legal, quality control and marketing motivations to maintain rigorous voluntary stewardship measures for field trials, as described above. For these

[5] https://www.alfalfa.org/pdf/CSBMPForRRA.pdf; http://www.syngenta-us.com/corn/enogen/grower; http://nabc.cals.cornell.edu/Publications/Reports/nabc_27/NABC27Report.pdf p.97

[6] https://www.alfalfa.org/pdf/GOZseed.pdf

[7] https://www.alfalfa.org/bio_growerzones.php

[8] Genetically Engineered Crops: Past Experience and Future Prospects. Committee on Genetically Engineered Crops: Past Experience and Future Prospects; Board on Agriculture and Natural Resources; Division on Earth and Life Studies; National Academies of Sciences, Engineering, and Medicine.

reasons, APHIS believes that developers would continue to use rigorous voluntary stewardship measures in field testing even when APHIS has determined that an organism does not pose a plant pest or noxious weed risk.

EPA has regulatory oversight of plant incorporated protectants (PIPs) such as Bt crops.[9] Currently, developers of PIPs must notify both EPA and APHIS of their intent to conduct field tests of the PIPs. If the field trials are on greater than 10 acres, EPA requires an experimental use permit (EUP). If the field trials are on 10 acres or less, APHIS assumes regulatory oversight. Under the proposed rule, APHIS would only require permits for PIPs planted on 10 acres or less if they present a plant pest or noxious weed risk or have not yet been evaluated by APHIS for such risk. This proposal would shift Federal oversight of small-scale (10 acres or less) outdoor plantings of PIPs to EPA. EPA may decide to require EUPs for all, some, or none of such PIPs, and may conduct inspections of all, some, or none of those PIPs under permit. EPA would need to develop a program to oversee small-scale testing of PIPs and issue regulations if warranted. APHIS is fully committed to coordinating with EPA in this matter in order to give EPA time to stand up such a program. APHIS understands that a memorandum of understanding (MOU) and services agreement may be necessary to provide personnel and other resources to assist EPA during the interim period while EPA implements its own program of oversight of outdoor planting of PIPs on 10 acres or less. APHIS recognizes that there are challenges associated with such a transition that also would require EPA to incur the costs associated with setting up a revised regulatory program. Further, it would require policies, procedures, and guidance regarding APHIS' interaction with EPA.

[9] Crops developed to be toxic to pest insects.

Under the provisions of the proposed rule, there is a possibility that APHIS could reach a determination that a GE plant that produces PMPIs is not a regulated organism. Such a plant would not be subject to field trial oversight by USDA, and could be planted before or without an evaluation by FDA or EPA.

APHIS has identified several options that have the potential for adequate Federal oversight of outdoor plantings of plants engineered to produce PMPIs. Under one option, a statute would be enacted, or existing statutory authority amended, to grant one or more Federal agencies explicit authority to provide oversight of outdoor plantings of all GE PMPI-producing plants and to evaluate GE PMPI-producing plants for all possible risks, beyond plant pest and noxious weed risks. For industrial-producing plants subject to EPA's jurisdiction, a second option is for EPA to develop a program to regulate industrial-producing plants and issue regulations if warranted. Under a third option, APHIS would enter into a MOU and services agreement with the appropriate Federal Agencies to provide personnel and other resources to assist those Agencies in their oversight of outdoor plantings of PMPI-producing GE plants, recognizing that Federal agencies may not have authority to require notification and/or oversight of the outdoor planting of some of these plants. Under a fourth option, those Federal Agencies would supply their own personnel and resources to exercise oversight of outdoor plantings of PMPI-producing GE plants, recognizing that Federal agencies may not have authority to require notification and/or oversight of the outdoor planting of some of these plants.

The rest of this section broadly describes expected direct impacts for the entities that would be principally affected, the biotechnology industry and the government (primarily USDA), and possible secondary effects for farmers who grow GE crops, farmers who grow organic or other crops, and international trade.

Direct Effects -- Biotechnology Industry

GE plants are subject to regulatory scrutiny and a battery of tests before commercialization. The process of experimentation, submission of experimental results, and regulatory review undertaken by biotech firms translate into compliance costs. The proposed rule would result in reduced field data collection, fewer reporting requirements, and lower management costs for preparation of permits. Petitions for non-regulated status—and the petition costs incurred—would be eliminated. There would be some new costs borne by regulated entities under the proposed rule including rule familiarization and recordkeeping. Recordkeeping cost tabulations are based on the information collection categories from the paperwork burden section of the rule, and are estimated to have a total cost of about $275,000. There have been about 1,100 unique entities who have applied for permits or notifications under part 340, and APHIS estimates that those entities would spend about 8 hours becoming familiar with the provisions of this rule at a total cost of about $576,000.

There is significant variation in current compliance costs because the requirements tend to vary from one regulatory submission (dossier) to another, depending on the crop modified, the novel trait introduced, and the type of regulatory approval pursued. These considerations drive differences in the number and type of field trials, analytical tests, bioinformatic analyses, animal studies and other comparative safety assessments (Kalaitzandonakes, et al. 2007).[10]

[10] APHIS is funding screenable marker research by Nicholas Kalaitzandonakes and his associates at the Economics and Management of Agrobiotechnology Center, University of Missouri. They are studying market impacts of screenable markers by surveying supply chain representatives, evaluating consumer reaction to the use of screenable markers based experimental test panels, and evaluating the potential impact of screenable markers on international trade based on surveys of international companies with branches in the United States and interviews of regulatory agencies overseas.

A difficulty in estimating the impact of the proposed rule for biotech developers is the fact that information on compliance costs is closely guarded and not publicly available (Phillips 2014; Kalaitzandonakes, et al. 2007). Two surveys provide estimates of the regulatory costs to the biotech industry of governmental oversight of new GE crop development in key producing and importing countries: Kalaitzandonakes, et al. (2007) and Phillips McDougall (2011). Both surveys were based on confidential data obtained from major biotech developers: Bayer CropScience, Dupont/Pioneer Hi-Bred, Monsanto Company, and Syngenta AG. In addition, Kalaitzandonakes, et al. (2007) included BASF Corporation data and Phillips McDougall (2011) included Dow AgroSciences data.

The Phillips McDougall (2011) study was designed to determine the cost and period of time associated with the discovery, development, and authorization of a new GE plant trait. The study reported costs in six main categories: discovery, construct optimization, commercial event production and selection, introgression breeding and wide area testing, regulatory science, and registration and regulatory affairs. For each category, the mean values of the company costs were determined based on survey responses. The entire process up to commercialization was taken into account. Information on four GE crops was collected: canola, cotton, soybean, and corn. The findings indicated that the average time required to discover, develop and authorize a new GE trait was 13.1 years, with an average cost of $142.8 million in 2015 dollars. Collectively, the costs of meeting all regulatory requirements amounted to $36.9 million in 2015 dollars, or 26 percent of the total.

Kalaitzandonakes, et al. (2007) estimated regulatory costs incremental to R&D expenses, providing greater insight to the potential cost savings for developers associated with the proposed rule. The estimated regulatory costs were found to be highly variable depending on the

company, ranging in 2015 dollars from about $8 million to $17.6 million for insect-resistant maize and from about $7 million to $16.5 million for herbicide-tolerant maize (table 2). These estimates are roughly one-half of the regulatory costs estimated by Phillips McDougall (2011).[11]

It should be noted that the above studies are based on surveys of private sector corporations, and involve the development, deregulation, and release in developed countries of high-value trait products such as herbicide-tolerant corn. The costs to not-for-profit institutions in development of GE crop plants with traits of low economic value can be substantially lower. For example, the cost to not-for-profit institutions in developing a GE potato variety resistant to late blight disease, for release in one developing country, was estimated at under $2 million over eight to nine years (Schiek, et al. 2016).

[11] APHIS does not have access to information that would account for this discrepancy.

Table 2. Developer Costs for Insect-Resistant Maize and Herbicide-Tolerant Maize

Cost Categories	Range of Costs Incurred ($1,000) [1]
General costs	
Preparation for regulatory process	23 - 57
Molecular Characterization	342 - 1,368
Compositional Assessment	855 - 1,710
Animal Performance and safety studies	342 - 963
Protein production and characterization	185 - 1,967
Protein safety assessment	222 - 975
Agronomic and phenotypic assessment	148 - 524
Production of tissues	775 - 2,508
ELISA development, validation and expression analysis	473 - 695
EU specific import (detection method, fees)	262 - 462
Canada specific costs	46 - 222
Stewardship	188 - 1,140
Toxicology (90-day rat)—when done	285 - 342
Facility and management overhead costs	638 - 5,130
Costs specific to Insect-resistant maize	
Non-target organism studies	114 - 684
EPA expenses for plant-incorporated protectants (PIP) (e.g., experimental use permit tolerances)	171 - 815
Environmental fate studies	36 – 912
Specific Firm-Level Totals Reported for Insect-resistant Maize	8,048 - 17,602 [2]
Costs specific to Herbicide-tolerant maize	
Herbicide residue study	120 - 627
Specific Firm-Level Totals reported for Herbicide-tolerant Maize	7,045 - 16,541 [2]

Source: Kalaitzandonakes et al., Compliance Costs for Regulatory Approval of New Biotech Crops. Nature Biotechnology 25 (5), pp 509; May 2007.
The costs of withdrawn events are not included in the figures. To preserve the confidentiality of firm-level data used, the means of the individual cost categories and total costs were not presented.
[1] Adjusted to 2015 dollars.
[2] Because an individual firm could have costs anywhere within the range of each cost category, the totals do not sum from the individual cost category figures shown.
Where the estimated cost for a general cost category differed between insect-resistant and herbicide-tolerant maize, we included the entire range.

Regulatory compliance involves a variety of activities such as field trials, analytical tests, bioinformatic analyses, animal studies, and other comparative safety assessments. Ranges of estimated costs for regulatory categories used in this analysis are shown in table 2. These cost estimates were based on activities associated with both insect-resistant and herbicide-tolerant

maize authorizations. In addition, three studies were unique to insect-resistant maize and one study was unique to herbicide-tolerant maize (Kalaitzandonakes, et al. 2007).

The costs shown in table 2 vary widely. Much of the difference among firms for the individual cost categories and total costs is the result of varying strategies followed by biotech developers as they pursue regulatory authorization of their innovations. Strategies are shaped by the developers' expectations of the appropriate number and types of field trials, analytical tests and assessment studies, and the number of events advanced through various regulatory stages to manage uncertainty.

As mentioned, under the Coordinated Framework for Regulation of Biotechnology, USDA, FDA, and EPA regulate GE plants and/or their products. For GE plants and/or their products such as herbicide-tolerant and insect-resistant corn, all three agencies have oversight. For a GE plant and/or its product used in human and animal food that does not include a plant-incorporated protectant (PIP), such as a variety of soybeans producing oil with altered fatty acid composition, USDA and FDA have oversight. A GE plant and/or its product not used for human or animal food but that contains a resistance gene is regulated by both USDA and EPA.[12] In some cases, neither FDA nor EPA has oversight of a GE plant or its product. Examples of articles regulated exclusively by USDA include horticultural plants such as petunias or carnations modified to produce different flower color, morphology, or longevity. Thus, we can consider two regulatory oversight scenarios: USDA either has sole regulatory authority or shares oversight with EPA and/or FDA. Following, we describe expected effects of the proposed rule on regulatory costs under both scenarios.

[12] While not all inclusive, this includes resistance to bacteria, fungi, virus, insects, and herbicides.

Estimates of current developer costs under the two regulatory oversight scenarios are shown in table 3. We note that the actual costs incurred by a specific firm are shaped by that developer's expectations of the appropriate number and types of field trials, analytical tests and assessment studies needed to advance through the various stages of consultation, deregulation and/or registration. Under sole oversight by USDA, compliance costs are estimated to range from $2.3 million to $12.7 million for a given GE trait. When USDA and also EPA and/or FDA have regulatory oversight of a given GE trait, costs are estimated to range from $4.6 million to $18 million for an herbicide-tolerant trait, and $4.8 million to $19.8 million for an insect-resistant trait.

Table 3. Estimated Current Developer Costs under Two Oversight Scenarios for Herbicide-tolerant Maize and Insect-resistant Maize, per trait, 2015 dollars

Activity	USDA	USDA & EPA and/or FDA
	($1,000)	
Preparation for hand-off of events into regulatory	23-57	23-57
Molecular characterization	342-1,368	342-1,368
Compositional assessment	N/A	855-1,710
Animal performance and safety studies	N/A	342-963
Protein production and characterization	185-1,967	185-1,967
Protein safety assessment	N/A	222-975
Agronomic and phenotypic assessments	148-524	148-524
Production of tissues	775-2,508	775-2,508
ELISA development, validation and expression analysis	N/A	473-695
Toxicology (90-day rat)	N/A	285-342
Facility & management overhead costs	638-5,130	638-5,130
Stewardship	188-1,140	188-1,140
Subtotal (1)	**2,299-12,693**	**4,476-17,379**
Herbicide residue study	N/A	120-627
Total for Herbicide resistance	N/A	**4,596-18,006**
non target organism study	N/A	114-684
EPA expenses for PIPs (e.g., EUPs, tolerances)	N/A	171-815
Environmental fate studies	N/A	36-912
Total for Insect resistance	N/A	**4,798-19,790**

(1) This subtotal represents the sum of costs for all activities that were in common between insect and herbicide resistant maize.

N/A: Not applicable

Under the proposed rule, permitting would only be required for those organisms that are thought to pose a plant pest or noxious weed risk. No USDA regulatory oversight would be needed once USDA has concluded from a risk assessment used to evaluate regulatory status that a plant pest or noxious weed risk is unlikely. APHIS' experience shows that most GE plants

evaluated are unlikely to pose a plant pest risk and do not merit regulatory oversight by the Agency under the PPA.

If USDA is the only agency having regulatory oversight for a particular trait, there are four activities that would not be required:

1. Preparation for hand-off of events into the regulatory process
2. Protein production and characterization
3. Agronomic and phenotypic assessments
4. Production of tissues

If EPA and/or FDA also have oversight, agronomic and phenotypic assessments would still be eliminated under the proposed rule. USDA currently uses the information gained from these assessments to evaluate whether a plant is a plant pest in accordance with its oversight authority. This information is not relevant to assessing food or environmental safety, the objectives of FDA and EPA oversight, respectively.

Furthermore, costs of preparing USDA dossiers and permits (included within facility and management overhead costs) would be reduced in all scenarios. These cost savings would come mainly from a reduction in time spent managing the process. We estimate that the reduction in management and administrative costs would be about $337,000 per trait, as shown by the difference in facility and management overhead costs in tables 3 and 4. This estimate is based on the assumption that two mid-level and one-upper level management employees work full-time conducting these processes for each trait.[13]

[13] May 2014 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics, http://www.bls.gov/oes/current/naics4_541700.htm#11-0000 on February 8, 2016. Based on North American Industry Classification System 541700, Scientific Research and Development Services.

We assume that even in cases where USDA as the sole regulatory agency concludes that regulation is not necessary, biotech developers would still incur costs for GE plant development. These costs would include molecular characterization, regulatory costs for international markets, stewardship, and facility and management overhead.[14] Table 4 shows estimated regulatory compliance costs under the proposed rule for the two oversight scenarios.

Table 4. Estimated Developer Costs under Two Oversight Scenarios, when APHIS concludes under the Proposed Rule that USDA regulation is not necessary, per Trait, 2015 dollars

Activity	USDA	USDA & EPA and/or FDA
	($1,000)	
Preparation for hand-off of events into regulatory	0	23-57
Molecular characterization	342-1,368	342-1,368
Compositional assessment	N/A	855-1,710
Animal performance and safety studies	N/A	342-963
Protein production and characterization	0	185-1,967
Protein safety assessment	N/A	222-975
Agronomic and phenotypic assessments	0	0
Production of tissues	0	775-2,508
ELISA development, validation and expression analysis	N/A	473-695
Toxicology (90-day rat)	N/A	285-342
Facility & management overhead costs	301-4,593	301-4,593
Stewardship	188-1,140	188-1,140
Subtotal[1]	**832-7,101**	**3,992-16,318**
Herbicide residue study	N/A	120-627
Total for Herbicide resistance	N/A	**4,111-16,944**
non target organism study	N/A	114-684
EPA expenses for PIPs (e.g., EUPs, tolerances)	N/A	171-815
Environmental fate studies	N/A	36-912
Total for Insect resistance	N/A	**4,313-18,729**

[1]This subtotal represents the sum of costs for all activities that were in common between insect and herbicide resistant maize.
N/A: Not applicable

[14] For APHIS' proposed risk assessment process for determining regulatory status, the biotech developer would be responsible for validating that the biotechnology organism corresponds to that which was intended. Therefore, molecular characterization would need to be performed even though the results would not need to be sent to APHIS. Similarly, companies would still need to bear stewardship costs to maintain best practices for field trials to maintain varietal purity and protect intellectual property interests.

Estimated cost savings with the proposed rule for the biotech developer under the two oversight scenarios are shown in table 5. APHIS estimates that biotech developers could save from $485,000 to $861,000 per GE trait when EPA and/or FDA also have oversight, and from $1.5 million to $5.4 million per GE trait when USDA would have been the only agency with oversight under current regulations. Since 1992, between 2 and 14 petitions have been processed (granted non-regulated status or the petition withdrawn) in a given year, with an average of just under 6. Because the rule is expected to spur innovation, we expect the number of new organisms developed annually to increase over time. In the following discussion, we assume the annual number of new GE organisms developed under the proposed rule would range from 6 (the current annual average) to 12 (twice this average), with 10 as an intermediate number. For GE organisms that would have solely required USDA oversight, the annual savings could range from $8.8 million to $32.4 million (6 new organisms), from $14.7 million to $53.9 million (10 new organisms), and from $17.6 million to $64.7 million (12 new organisms). For organisms that are submitted for multi-agency evaluation, the annual savings could range from $2.9 million to $5.2 million (6 new organisms), from $4.9 million to $8.6 million (10 new organisms), and from $5.8 million to $10.3 million (12 new organisms). Because of the larger regulatory cost savings for GE crops that require only USDA oversight, the proposed rule may provide impetus to the development of new horticultural varieties. Very few such crops have acquired non-regulated status, presumably because the costs of acquiring non-regulated status have been too high in relation to a relatively small market.

Table 5. Estimated Developer Cost Savings under Two Oversight Scenarios, when APHIS concludes under the Proposed Rule that USDA regulation is not necessary, per Trait, 2015 dollars

Activity	USDA	USDA & EPA and/or FDA
	($1,000)	
Preparation for hand-off of events into regulatory	23-57	0
Protein production and characterization	185-1,967	0
Agronomic and phenotypic assessments	148-524	148-524
Production of tissues	775-2,508	0
Facility & management overhead costs	337	337
Total	**1,468-5,393**	**485-861**

APHIS is proposing several exclusions that may lead to additional modest cost savings to the regulated community, but substantial resource savings for APHIS. These exclusions are intended to obviate the need for APHIS to conduct a risk assessment in cases where the modified organisms are equivalent to what otherwise would be achieved through conventional breeding. As APHIS completes risk assessments under the proposed rule, similar organisms would not need to be subsequently reviewed by APHIS, saving the Agency from spending resources on repetitive unproductive work. These savings are discussed further under the section 'Government.'

While the proposed rule would likely shorten the evaluation process for USDA, it is not expected to affect the time needed by FDA or EPA. When FDA and/or EPA also have a regulatory role, time savings would be realized in those instances in which USDA process takes the longest time. In a number of cases, USDA deregulation has lagged behind the consultation process of FDA and the registration process of EPA. For 17 of 22 recent new plant varieties, FDA's consultation was completed before USDA completed its determination of non-regulated status. In at least 6 other cases, FDA consultation and EPA registration were both completed

before the USDA process. The new varieties were for the major export crops, corn, cotton, soybeans, and alfalfa. The average time needed to acquire non-regulated status when FDA and/or EPA also have oversight may therefore decrease somewhat under the proposed rule. It is also worth noting that a determination of non-regulated status by USDA may not exempt the organism from State and local laws and regulations issued to address concerns other than plant pest or noxious weed risk.

When USDA is the only agency with oversight, the evaluation process is expected to take a month or less for organisms that are unlikely to pose plant pest or noxious weed risk. This would be a significant time savings. APHIS has completed 8 petitions requesting non-regulated status since 2013. The time required to complete these 8 petitions averaged about 16 months, and ranged from 7 to 24 months.

The proposed rule may also indirectly benefit public sector agricultural GE research. University researchers have often commented that the cost of regulation thwarts their ability to use modern methods to innovate and improve crop varieties. This rule is expected to lower the cost of conducting field trials and completing USDA regulatory process. To that extent, it may spur innovation by public sector researchers. Such innovation may ultimately benefit private sector biotech companies, farmers, and consumers.

Benefits may also accrue from the greater regulatory certainty that would result from the proposed risk assessment process used to determine regulatory status under USDA. Biotech developers, particularly start-up companies, depend on raising venture capital at the onset to fund their innovations. Raising venture capital is especially difficult if regulatory concerns remain an obstacle. Under the proposed rule, that obstacle would be removed for cases where APHIS concludes that a particular organism is unlikely to pose a plant pest or noxious weed risk. Under

the proposed risk assessment process, companies should need fewer resources to conduct USDA specific tests and prepare USDA dossiers and should be better able to raise venture capital to pay for field trials. In this way, the proposed rule is expected to spur innovation. Because regulatory costs can be a barrier to entry into the biotech industry for small firms and a barrier to the introduction of products with small potential markets, the advantages gained from the proposed risk assessment process may be particularly evident in those instances.

In sum, with a USDA permit not expected to be required for most GE organisms under the proposed rule, in contrast to the current process, we anticipate both direct and indirect economic benefits for the biotech industry. First, direct regulatory costs to biotech developers would be reduced for those organisms that are considered unlikely to pose a plant pest or noxious weed risk. Savings to the regulated community would result from a reduced need to collect field data, fewer reporting requirements, and lower management costs when compared to current costs when applying for permits and petitions. Second, indirect benefits are expected to result from a quicker USDA regulatory process. These include reduced regulatory uncertainty that may facilitate small companies' ability to raise venture capital, and reduced regulatory requirements that may increase greater participation by the public sector in GE research. The latter effects can be expected to spur GE innovations.

Direct Effects -- Government

Benefits of the proposed rule would include more efficient regulation of entities by APHIS under part 340 by implementing risk-based regulation and the noxious weed provision of the PPA. The proposed rule would result in a decrease in the level of scrutiny of GE organisms by the Agency that are unlikely to pose plant pest and noxious weed risk and increased scrutiny by the Agency of those that do present risks, or that are unevaluated by APHIS for such risks.

APHIS costs of regulating GE organisms that pose plant pest and/or noxious weed risks are expected to change under the proposed rule. At present, costs to the Agency are incurred in reviewing and issuing permits and notifications, reviewing petitions and developing environmental impact statements, conducting environmental assessments, and conducting field inspections and compliance actions. The impact of eliminating the notification process is not expected to result in an increase in permits because plants eligible for this process would most likely not be subject to permitting requirements based on the risk assessment used to evaluate regulatory status.

Annual APHIS personnel costs of conducting GE activities under current regulations that would be affected by the proposed rule total about $5.6 million, out of annual funding of biotechnology regulatory services of about $19 million. This estimate is based on activities in 2015, when APHIS processed 164 importation and interstate movement permits and 190 environmental release permits; conducted 800 inspections; and issued 39 import permits and 104 interstate movement permits; and acknowledged 97 import notifications, 325 interstate notifications, 232 combined interstate and release notifications, and 102 release notifications.

Under the proposed rule, annual costs are expected to range from $2.5 million to $7.8 million, depending on the volume of permits, weed risk assessments, inspections, and NEPA/ESA activities (table 6 and appendix tables). For both lower- and upper-bound scenarios, there would be no notification, petition, courtesy permit, or "Am I Regulated" (AIR) processes.[15] Permits for importation/interstate movement and permits for environmental releases are each expected to number from 100 to 200. The courtesy permit and accompanying Letter of No

[15] "Am I Regulated" is a process whereby the biotech industry can determine whether a specific trait is regulated by APHIS by entering information in BRS' permit system.

Jurisdiction, valid for three years and country-specific, would be replaced by a Letter of No Permit Required, valid in perpetuity for imports from any country. APHIS resources needed to issue a Letter of No Permit Required would be about the same as currently required to issue a courtesy permit; however, there would be savings realized over time, as fewer are issued.

The number of employees needed to conduct weed risk assessments is expected to range from 4 GS-13 and 1 GS-14 (lower-bound) to 7 GS-13 and 2 GS-14 (upper-bound). Inspections are expected to range from the current 800 per year to 1,500 with all sites inspected, and inspection time may increase by 50 percent. NEPA/ESA activities may range from 50 percent of the current level to double the current level. We assume that BRS staffing would remain at the current level, with resources made available by the elimination of notifications and petitions reallocated to risk assessments and inspections.

Table 6. APHIS Staff Costs, including Benefits and Overhead, under Current Regulations and the Proposed Rule, by Activity, 2015 dollars

	Current Regulations		Proposed – Lower Bound		Proposed – Upper Bound	
	Annual Number	Cost ($1,000)	Annual Number	Cost ($1,000)	Annual Number	Cost ($1,000)
Notifications[1]	756	203	0	0	0	0
Petitions for non-regulated status [2]	5	2,130	0	0	0	0
Permits, import and interstate movement[3]	190	239	100	139	200	261
Permits, movement and environmental release[3]	164		100		200	
Courtesy permits	650	19	0	0	0	0
Letters of No Permit Required[4]	0	0	91	3	91	3
"Am I Regulated" Process[5]	10	7	0	0	0	0
Weed Risk Assessment[6]	0	0		700		1,265
Compliance and Inspections[7]	800	361	800	361	1,500	1,014
NEPA/ESA[8]	1,110	2,648	One-half of current	1,324	Twice as many as current	5,297
TOTAL		5,607		2,527		7,840

[1] See Appendix Table 5.
[2] See Appendix Table 7.
[3] See Appendix Table 6.
[4] Average number and cost per year over 10 years. About the same staff time would be required for a Letter of No Permit Required as is currently required for a courtesy permit: 25 minutes by a GS-12 and 5 minutes by a GS-14. Because a Letter of No Permit Required would not be country-specific and would not have a date of expiration, their number is expected to decrease over 3 years: year 1, 500 letters; year 2, 250; and year 3 and after, 20. A total of 910 over the first 10 years that the rule is in effect yields an average of 91 letters per year.
[5] See Appendix Table 4.
[6] See Appendix Table 2. The number of weed risk assessments that would be conducted per year under the proposed rule is difficult to estimate, but could range between 50 and 500.
[7] See Appendix Table 3.
[8] See Appendix Table 1.

APHIS would also likely incur modest additional costs in conducting outreach activities for the proposed rule, developing guidance documents to ensure that the regulated community is

familiar with the requirements of the rule, updating the inspection manual, and providing certain staff training in regard to the regulatory revisions. APHIS estimates that the public outreach, guidance and training would cost about $88,000. Requests for regulatory status and response letters under the proposed rule could be handled in a manner similar to the current 'Am I Regulated' process outside the electronic permitting system without new costs.

When plants are genetically engineered to produce PMPIs, the plants and the pharmaceutical and/or industrial products they produce may fall within the purview of multiple regulatory Agencies: APHIS, EPA, and/or FDA.

Under the current regulations in 7 CFR part 340, APHIS requires permits, as opposed to Notifications, for the environmental release of all GE plants that meet the definition of a regulated article and produce PMPIs. APHIS exercises oversight of all outdoor plantings of these regulated PMPI-producing plants. This oversight includes establishment of appropriate environmental release conditions, inspections, and monitoring. Products obtained from PMPI-producing plants may be regulated by FDA (authority over pharmaceuticals) or EPA (chemical substances as defined by the Toxic Substances Control Act (TSCA)), depending on their intended use. To date, producers of PMPI-producing plants, or products derived from such plants, have not intended for such plants or plant products to be used for human or animal food. However, if such a plant or plant product is used for human or animal food, the food would be subject to applicable statutory and regulatory requirements under the Federal Food, Drug, and Cosmetic Act.

To date, PMPI-producing GE plants regulated by APHIS have been genetically engineered using a plant pest as the donor, vector, or vector agent, and thus fall under the scope of regulated article in the current regulations in 7 CFR part 340. However, under the provisions

of this proposed rule, as discussed at greater length later in this document, a GE plant that is developed using a plant pest as a vector, vector agent, or donor of genetic materials would not necessarily be a regulated organism. Rather, the GE plant would be a regulated organism if it had a plant/trait combination that the Agency has not yet evaluated for plant pest and/or noxious weed risk, if it has received DNA from a taxon that contains plant pests and the DNA from the donor organism is sufficient to produce an infectious entity capable of causing plant disease or encodes a compound known to be pathogenesis-related that is expected to cause plant disease symptoms, or if it was evaluated and found to represent plant pest or noxious weed risks. Additionally, APHIS' evaluations of GE plants for plant pest or noxious weed risk would generally not require data from outdoor plantings.

Even if the plant represents a new plant/trait combination not previously reviewed, there is a likelihood that most, if not all, GE PMPI-producing plants that are currently under APHIS permits could be determined not regulated under the provisions of the proposed regulations after a regulatory status evaluation because they do not represent risks as a plant pest or noxious weed. Thus, such plants could be grown outdoors without the need for permits and without APHIS oversight.

Federal oversight of outdoor plantings of PMPI-producing plants, however, could be necessary to prevent unlawful entry into the food supply of material from such plants. Establishing growing and handling conditions to confine such plants, and inspecting to ensure such conditions are followed, may enable corrective actions before material from the plants is inadvertently released and causes public health or economic impacts. One of the reasons APHIS' oversight of such crops has been an important part of the coordinated framework for oversight of GE plants is that companies are not necessarily required to notify FDA or EPA

when the company plants PMPI-producing plants. For example, for PMPI-producing plants whose products fall under FDA authority, FDA has no regulations governing planting of such crops. For crops genetically engineered to produce pharmaceuticals, companies only have to come to FDA when they have reached the point that they are ready to begin clinical trials with the pharmaceutical derived from the plant. This could be years after they first started growing the pharmaceutical-producing plant in the field.

Under TSCA, EPA has requirements for new chemical substances, including industrial compounds produced in genetically engineered plants. However, given existing APHIS oversight, EPA does not currently have an oversight program nor regulations for genetically engineered plants with industrial compounds.

A gap in Federal oversight of PMPI producing-plants could result in the intentional or inadvertent introduction into the human or animal food supply of unevaluated pharmaceutical or industrial PMPI products, even when the principal purpose of the plants is not for human or animal food use. For example, a company could self-determine that the PMPI produced by the plant was generally recognized as safe (GRAS), and therefore conclude it had no legal obligation to keep surplus PMPI-producing plants out of the human or animal food supply, to keep such PMPI-producing plants from spreading pollen to plants grown for human and animal food purposes, or even to notify any Federal agency that they were planting such crops. In addition to potential food safety risks posed by such plants should they enter the food supply, a gap in Federal oversight could generate concerns from the general public regarding the safety and wholesomeness of the human or animal food supply, which could adversely impact agricultural interests.

APHIS has identified several options that have the potential for adequate Federal oversight of outdoor plantings of plants engineered to produce PMPIs. Under one option, a statute would be enacted, or existing statutory authority amended, to grant one or more Federal agencies explicit authority to provide oversight of outdoor plantings of all GE PMPI-producing plants and to evaluate GE PMPI-producing plants for all possible risks, beyond plant pest and noxious weed risks. For industrial-producing plants subject to EPA's jurisdiction, a second option is for EPA to develop a program to regulate industrial-producing plants and issue regulations if warranted. Under a third option, APHIS would enter into a MOU and services agreement with the appropriate Federal Agencies to provide personnel and other resources to assist those Agencies in their oversight of outdoor plantings of PMPI-producing GE plants, recognizing that Federal agencies may not have authority to require notification and/or oversight of the outdoor planting of some of these plants. Under a fourth option, those Federal Agencies would supply their own personnel and resources to exercise oversight of outdoor plantings of PMPI-producing GE plants, recognizing that Federal agencies may not have authority to require notification and/or oversight of the outdoor planting of some of these plants.

Over the last three years, APHIS has conducted an average of 44 PMPI site inspections. Accounting for pre-inspection preparation, actual inspection time, travel time and travel costs, the administration of the inspections including report writing and correspondence, as well as miscellaneous expenses including permit insurance, APHIS estimates that current PMPI inspections have cost roughly $35,000 in total annually, or about $800 each on average. A similar government expenditure could be expected under any of the above PMPI oversight scenarios.

If a Federal agency were to supply its own personnel and resources to exercise oversight over PMPIs, there will be costs incurred in setting up oversight programs, particularly if the Federal agency does not currently conduct field inspections if a PMPI is subject to APHIS regulations. Any of the PMPI oversight options may necessitate a Federal agency changing policies, regulations, and/or procedures, adding staff and expertise, with the corresponding costs based on how such changes are implemented by the Agency.

Certain plants are genetically engineered to produce plant-incorporated protectants (PIPs), meaning that they produce pesticides. PIPs fall under the regulatory oversight of EPA. However, currently only APHIS exercises regulatory oversight of PIP plantings on 10 acres or less of land. Under the proposed rule, APHIS would only require permits for PIPs planted on 10 acres or less if they present a plant pest or noxious weed risk or have not yet been evaluated by APHIS for such risk. Under the current regulations in 7 CFR part 340, APHIS requires permits or notifications for the environmental release of all GE plants that meet the definition of a regulated article and produce PIPs. APHIS exercises oversight of all outdoor plantings of these regulated PIP-producing plants. This oversight includes establishment of appropriate environmental release conditions, inspections, and monitoring.

To date, PIP-producing GE plants regulated by APHIS have been genetically engineered using a plant pest as the donor, vector, or vector agent, and thus fall under the scope of regulated article in the current regulations in 7 CFR part 340. However, under the provisions of this proposed rule, as discussed at greater length later in this document, a GE plant that is developed using a plant pest as a vector, vector agent, or donor of genetic materials would not necessarily be a regulated organism. Rather, the GE plant would be a regulated organism if it had a plant/trait combination that the Agency has not yet evaluated for plant pest and/or noxious weed

risk, or if it has received DNA from a taxon that contains plant pests and the DNA from the donor organism is sufficient to produce an infectious entity capable of causing plant disease or that encodes a compound known to be pathogenesis-related that is expected to cause plant disease symptoms. Additionally, APHIS' evaluations of GE plants for plant pest or noxious weed risk would generally not require data from outdoor plantings.

Even if the plant represents a new plant/trait combination not previously reviewed, there is a likelihood that many GE PIP-producing plants that are currently regulated under APHIS permits or notifications could be determined not regulated under the provisions of the proposed regulations after a regulatory status evaluation because they do not represent risks as a plant pest or noxious weed. Thus, such plants could be grown outdoors without the need for an APHIS permit and without undergoing APHIS oversight.

If field trials are on greater than 10 acres, EPA requires an EUP. If the field trials are on 10 acres or less, APHIS assumes regulatory oversight. Under the proposed rule, APHIS would only require permits for PIPs planted on 10 acres or less if they present a plant pest or noxious weed risk or have not yet been evaluated by APHIS for such risk. This proposal would shift Federal oversight of small-scale (10 acres or less) outdoor plantings of PIPs to EPA. EPA may decide to require EUPs for all, some, or none of such PIPs, and may conduct inspections of all, some, or none of those PIPs under permit. EPA would need to develop a program to oversee small-scale testing of PIPs and issue regulations if warranted. As described above, current inspection costs incurred by APHIS average roughly $800 per inspection.

APHIS is fully committed to coordinating with EPA in this matter in order to give EPA time to stand up such a program. APHIS understands that a MOU and services agreement may be necessary to provide personnel and other resources to assist EPA during the interim period

while EPA implements its own program of oversight of outdoor planting of PIPs on 10 acres or less. APHIS recognizes that there are challenges associated with such a transition that also would require EPA to incur the costs associated with setting up a revised regulatory program. Further, it would require policies, procedures, and guidance regarding APHIS' interaction with EPA.

Summary of Expected Direct Impacts

Table 7 provides a summary statement of the expected direct benefits and costs of the proposed rule: compliance cost savings for the biotechnology industry, and a reallocation of APHIS Biotechnology Regulatory Services staffing resources.

Table 7. Expected Annual Benefits and Costs of the Proposed Rule for the Biotechnology Industry and for USDA, 2015 dollars

Entity			
Biotechnology Industry	Costs ($1,000)		
Developer costs (recordkeeping and rule familiarization)[1]	851		
	Cost Savings ***per Trait*** ($1,000)		
Developer Savings [2]		Proposed Rule, lower bound	Proposed Rule, upper bound
USDA sole regulatory agency		-1,468	-5,393
USDA with FDA and/or EPA oversight		-485	-861
APHIS Biotechnology Regulatory Services	Costs ($1,000)		
Costs for public outreach, training, and epermitting[3]	88		
Activities affected by the rule	Current Rule	Proposed Rule, lower bound	Proposed Rule, upper bound

Notifications	203	0	0
Petitions	2,130	0	0
Interstate movement and environmental release permits	239	139	261
Courtesy permits	19	0	0
Letters of No Permit Required	0	3	3
"Am I Regulated" Process	7	0	0
Weed risk assessments	0	700	1,265
Compliance and Inspections	361	361	1,014
NEPA/ESA	2,648	1,324	5,297
TOTAL[4]	**5,607**	**2,527**	**7,840**

[1] Becoming familiar with the rule are one-time costs.

[2] These savings are shown on a per trait basis. If between 6 and 12 GE organisms are developed each year that would have solely required USDA oversight, annual savings could range from $9 million to $64.8 million. If between 6 and 12 new GE organisms per year are submitted for multi-agency evaluation, the annual savings could be from $2.9 million to $10.3 million.

[3] Requests for regulatory status and response letters under the proposed rule could be handled in a manner similar to the current 'Am I Regulated' process outside the electronic permitting system without new costs.

[4] Annual staffing costs of APHIS Biotechnology Regulatory Services total about $19 million.

Secondary Effects -- Farmers who grow GE Crops

If the regulatory relief expected under the proposed rule spurs innovation, farmers who adopt GE crops may benefit by having access to a wider variety of traits to meet their specific needs in managing agricultural pests and diseases, as well as to additional new GE crop species.

The adoption of GE crops in the United States has generally reduced costs and improved profitability at the farm level (Brookes and Barfoot 2013; Fernandez-Cornejo et al. 2014; Klümper and Qaim 2014; Brookes and Barfoot 2015). U.S. farmers have realized higher incomes due to their use of GE crops, totaling approximately $58.4 billion in extra income between 1996 and 2013 (Brookes and Barfoot 2015).

In comparison to the status quo, we expect the proposed revisions to APHIS' regulation of GE organisms would more readily help expand this history of improved farm-level profitability to include a number of crop species for which GE varieties have yet to be

developed. As we mentioned above, biotech developer regulatory costs are expected to be lower than the status quo under the proposed rule, potentially spurring innovation, especially among small companies and universities. Among the types of innovations expected are crops with greater resistance to disease and insect pests, greater tolerance of stress conditions such as drought, high temperature, low temperature, and salt, and more efficient use of fertilizer. These types of traits can lower farmer input costs (water, fertilizer, pesticide) and increase yields during times of adverse growing conditions.

Secondary Effects -- Organic and Natural Farms

Some consumers choose not to purchase products derived from GE crops and instead purchase commodities such as those labeled "non-GMO" or organic. When crops intended for the non-GE or other identity-preserved marketplace contain unintended GE products, the value of the non-GE or other identity-preserved product is diminished. Organic producers are concerned about "lost markets, lost sales, lower prices, negative publicity, withdrawal of organic certification, and product recalls" (Hewlett 2008).

There is relatively little information detailing the economic harm incurred by the organic industry because of the unintended presence of GE products. The 2012 Census of Agriculture reported the increase over time of losses incurred by certified organic farms in the United States as a result of the presence of GE organisms. Between 2001 and 2005, one farm in Iowa and one in Utah reported losses due to the presence of GE organisms. The economic value of the losses was not reported. Between 2006 and 2010, nine farms reported losses due to the presence of GE organisms. These losses totaled $68,974, with an average loss per farm of $7,664. Three of the farms were in Wisconsin, two were in Iowa, and one each was in Illinois, Kansas, Missouri and Nebraska. Between 2011 and 2014, 87 farms reported an average farm loss of $70,099 for a total

$6.1 million.[16] In 2015, 32 farms reported a total of $520,671, with an average loss of $16,271. In 2015, the total value of sales of certified organic field crops was $660 million.[17]

GE traits can be acquired through pollination of non-GE flowers by GE pollen produced in neighboring fields of GE varieties. Vegetable seed production usually takes place in limited areas where large isolation distances are employed to preserve varieties. For example, pollination of non-GE sugar beets, table beets, and Swiss chard by GE pollen has to our knowledge not been a recurring problem because of the stewardship and best practices employed by the industry. Other field crops such as beans, lentils, and peas are self-fertilizing and therefore unlikely to be affected.

In addition to the risk posed by GE pollen, non-GE grain crops are susceptible to unintended GE presence through commingling of the harvested seed. Commingling of seed can occur through use of the same equipment or conveyances not thoroughly cleaned. Vegetable crops are unlikely to present a commingling issue because the crops are harvested prior to flowering and the harvested materials are large (carrots, heads of lettuce and cabbage), typically identity-preserved, and not likely to be commingled accidentally through use of the same equipment or conveyances.

Farmers catering to the non-GE market (growers of organic or other identity-preserved crops) for crops with no current commercialized GE varieties could be negatively impacted by the proposed rule if it contributes to an increase in the variety of GE plant species grown in the

[16] 2012 Census of Agriculture. Organic Survey (2014) Vol. 3 Special Studies Part 4, Table 45. Value of Organic Crops Loss from Presence of Genetically Modified Organisms (GMOs) -- Certified Organic Farms: 2014 and Earlier Years http://www.agcensus.usda.gov/Publications/2012/Online_Resources/Organics/organics_1_045_045.pdf
[17]Certified Organic Survey, 2015 Summary (September 2015). Table 15. Value of certified Organic Crop Loss from Presence of Genetically Modified Organisms (GMOs) and Genetically Engineered (GE) Material: 2015 and Earlier Years. And Table 9. Certified Organic Field Crops Harvested and Value of Sales: 2015.

United States. The non-GE crops most likely to be negatively impacted are grain crops such as wheat, rice, barley, sorghum, and oats, for which no GE varieties have been commercialized to date.[18] Other crops such as hops and peanuts, could also be affected.[19] Table 8 shows the quantity and value of certain organic field crops produced on certified and exempt organic farms in 2014.[20] For crops such as corn, soybean, cotton, sugar beet, and canola, GE varieties already represent greater than 90 percent of the planted acreage in the United States and the proposed rule is unlikely to spur innovation in new varieties that would significantly alter these percentages.

One factor difficult to predict is the economic impact of gene editing on the non-GE market. It is likely that gene-editing will be a method excluded from organic production, but the method of choice to modify GE products. In most cases, these GE products may not be identifiable by testing. Even though such products may not be eligible for the organic label, they may not result in any economic harm to organic or non GE producers from unintended presence.

[18] A variety of GE rice has been deregulated but not commercialized.
[19] The extent to which some crops are harvested after flowering affects how much of the crop would be potentially affected by the unwanted presence of GE traits.
[20] Farms and businesses with gross agricultural income from organic sales of less than $5,000 per year are considered "exempt" operations. They do not need to be certified in order to sell, label, or represent their products as organic, nor do they not need to develop a written organic system plan. However, they must follow all other USDA organic regulations.

Table 8. Organic Field Crops susceptible to Cross Pollination or Commingling for which there are no commercialized GE Varieties, Number of Farms, Quantity Harvested, and Value of Sales – Certified and Exempt Organic Farms, 2015

Crop	Farms[1]	Quantity (million)	Value of Sales (million dollars)
Barley for grain or seed (bushels)	353	2.2	19.3
Buckwheat (bushels)	61	0.1	1.5
Flaxseed (bushels)	52	0.1	3.8
Hops (pounds)	33	0.6	5.0
Oats for grain or seed (bushels)	583	1.6	10.5
Peanuts (pounds)	22	16.5	10.9
Proso millet (bushels)	39	0.1	1.1
Rice (hundred weight)	106	1.2	41.3
Rice, wild (hundred weight)	10	0.0	3.0
Rye for grain or seed (bushels)	151	0.1	1.4
Sorghum for grain or seed, including milo (bushels)	39	0.3	2.9
Sorghum for silage or greenchop (tons)	26	0.0	1.1
Sunflower seed (pounds)	52	4.2	1.9
Wheat (bushels)	948	7.9	108.6
TOTAL[2]	***2,483***		***212.5***

Source: 2015 Organic Survey. USDA, NASS.

[1] Organic farms with $5,000 or more in sales.

[2]Quantity and value totals include "exempt" farms having less than $5,000 in annual sales.

Organic and other identity-preserved crops generally receive a price premium in comparison to conventionally grown crops, a premium lost with the unintended presence of GE traits. This is to be expected because some consumers strongly prefer them over their conventional counterparts (Loureiro, et al. 2001). Organic price premiums are also expected because organic production involves additional risks (Klonsky and Greene 2005) and higher costs (McBride and Greene 2008). Born (2005) noted that "prices for organic grains and oilseeds were about double the conventional prices from 1995 to 2003." Crowder and Reganold (2015) examined the financial performance of organic and conventional agriculture by conducting a meta-analysis of data from 44 studies involving 55 crops grown on 5 continents over a 40-year period. They found that median premiums were 32 percent for organically grown crops and 29 percent for organic systems (averaged across all crops in the system). Carlson and Jaenicke (2016) found premiums for fresh vegetables ranging from 7 to 44 percent, with many around 30 percent. It is the premium above the price for conventional crops that is lost by the unintended presence of GE traits. In addition to the loss of premium value when the crop cannot be sold as organic or non-GE, the producer may also pay for transporting back the rejected consignment, essentially doubling freight costs.

If the proposed rule leads to the development and adoption by growers of new GE varieties that increases the incidence of unintended GE presence in other crops, the affected producers would be negatively affected. Because organic crops and other non-GE crops can always be sold as conventional crops, the price premium above the conventional price represents a measure of the harm caused by the unwanted presence of GE traits. The risk to organic and non-GE growers from cross-pollination would depend on the extent to which the new GE

varieties of crops that could result in cross-pollination or commingling are commercialized, the degree to which those new varieties are adopted, and the proximity of fields where the new GE crops are grown to organic or other identity-preserved crops.

Secondary Effects -- Unauthorized Releases

Unauthorized releases of regulated GE crop plants and the entry of regulated plant material in the commercial food and feed supply have occurred. While such incidents may occur again, it is expected that such incidents will be rare. Financial losses resulting from unauthorized releases are difficult to quantify due to a variety of factors determining the market price of agricultural commodities. However, a couple of examples are provided. One example is that of the well-publicized StarLink corn incident. While not explicitly an unauthorized release for APHIS, it serves as an example of potential costs. StarLink corn was deregulated by APHIS, yet did not have an established tolerance for food consumption set by EPA. In 1998, EPA registered StarLink corn for commercial use, provided that all grain derived from StarLink corn was directed to domestic animal feed or to industrial uses (e.g., biofuels). It was not authorized for food uses, and there were no established tolerance limits for human food. In September 2000, residues from StarLink corn were detected in taco shells, indicating that it had entered the human food supply.

It is estimated that this incident resulted in $298 million to $964 million in lost revenue for producers in market year 2000/2001 (Lin, Price and Allen 2003). A separate study estimated that the presence of StarLink in the food supply caused a 6.8% drop in the price of corn, lasting for 1 year. In total, nearly 300 food products were taken off the market (Lin, Price et al. 2003), not necessarily because StarLink corn had been detected in all of the products, but as a precaution taken by the manufacturers of the products. The U.S. share of corn imports into Japan for starch use declined from 93 percent to 62 percent during November 2000 through

March 2002. South Korea's imports of U.S. corn for food manufacturing during the same year-and-a-half period were down 53% from the comparable period before the incident, a decline of about 1.2 million tons (Lin, Price et al. 2003).

Similarly, GE Liberty Link rice 601 (LLRICE 601), which was regulated by APHIS, was detected in samples taken from commercial long grain rice. While both USDA and FDA reviewed the available scientific data and concluded that there were no human health, food safety, or environmental concerns, the economic consequences of the unauthorized release were substantial. The market costs of commingling of APHIS regulated LLRICE 601 with non-GE rice, worldwide, including the costs associated with the loss of export markets, seed testing, elevator cleaning, and food recalls in countries where the variety of rice had not been approved, are estimated to have ranged from $741 million to $1.3 billion (US-GAO 2008).

While the proposed rule would shorten the regulatory process for USDA and potentially spur innovation in GE products, it is not expected to affect the overall pace of commercialization of GE traits that require multi-agency oversight. The commercialization of a GE trait can affect international trade in a commodity.

International approval of commercialized GE traits is critical to minimizing trade disruptions. Asynchronous approval occurs when adoption of a GE trait takes place in the United States prior to approval of that trait in an export market. Even the trace presence of a GE trait in U.S. exports to markets for which it has not been approved can result in market disruptions and corresponding producer losses, as have happened with U.S. exports of corn, soybeans, and alfalfa. As an example, China refused entry of corn with trace amounts of a strain called Syngenta MR-162 that it had not approved. The embargo, from November 2013 until China approved the use of MR-162 on December 16, 2014, affected corn sales valued at

approximately $5 billion and prompted law suits in 22 States between U.S. producers and Syngenta.[21]

A major obstacle to the commercialization of new GE crops is acquiring international approval. The cost of forgone benefits stemming from even a relatively brief delay in product release overshadows both research and regulatory costs (Bayer, et al. 2010; Phillips 2014; and Pray, et al. 2005). The opportunity costs of the regulatory process include both the out-of-pocket expenses and the associated expense of delays in commercialization, both for biotech companies and consumers. In addition to the costs associated with regulatory processes, biotech companies also incur debt servicing charges while revenues are delayed. Growers forgo income that could be earned, and consumers similarly forgo benefits of lower priced or higher quality products (Phillips 2014).

Alternatives to the Proposed Rule

APHIS considered three alternative regulatory approaches to revising 7 CFR part 340. In addition to a no-action alternative (Alternative 1) and the preferred alternative (Alternatives 2), APHIS also considered comprehensive regulations (Alternative 3).

It is worth noting that APHIS also identified several other alternatives, but, after evaluating them relative to the Agency's PPA authorities, as well as their potential efficacy and feasibility in fulfilling the purpose and need for revisions of the regulations, dismissed these other alternatives and did not consider them further. A discussion of these dismissed alternatives

[21] Marshall, Vincent. Syngenta corn lawsuit moves forward. Dodge City Daily Globe. June 4, 2015

is found in the draft programmatic environmental impact statement prepared for the proposed rule.

An overview of Alternative 3 is presented below.

Alternative 3. Comprehensive Regulations

Under this alternative, APHIS would substantially increase oversight of GE organisms relative to the No Action and Preferred Alternative. This alternative is similar to the proposed rule in that it incorporates noxious weed authority, uses the revised definitions for "genetic engineering" and "GE organism," and conducts risk analyses via a PPRA and WRA. However, it expands the scope of regulation to encompass the potential economic impacts of GE plants on non-GE plants. The mere presence of GE plant materials (e.g., pollen, seed, grain dust) in non-GE plants and their products would be considered a harm to agricultural interests and subject to regulation under 7 CFR part 340, there would not need to be evidence of biological harm. In effect, APHIS would serve as a wide-scale permitting authority overseeing the production of many of the commercial GE plants currently grown, and those that would be grown under this alternative, including GE organisms regulated under the proposed rule.

Hence, noxious weed harm would be expanded to include economic harm from the unintended presence of GE traits in other plants especially resulting from cross-pollination. GE organisms that are unlikely to pose a plant pest or noxious weed risk under current regulations would be evaluated for potential economic harm. Organisms with the potential to cause such harm would require a permit for environmental release, to include commercial crop production. The permit conditions for these organisms would be specifically designed to limit cross-pollination between GE organisms and non-GE plants by specifying isolation distances; require management of volunteer plants to prevent GE plants from flowering in abandoned,

fallow, and rotated fields; and ensure that only GE plants that have been granted international approval in the major export markets are grown in the United States.

Registration and Pinning System: All non-GE plant producers (conventional, organic, and other identity-preserved) that wish to receive protections from injury or harm due to the mere presence of noxious weeds provided under the regulations would need to be registered with APHIS to confirm that they are legitimate business entities. A registration system for non-GE plant producers would be developed, and non-GE plant producers would need to register their production systems with APHIS to establish authenticity and qualify for protections under 7 CFR part 340. In addition, a voluntary national web-based pinning map would be developed to identify the location and acreage of GE and non-GE plants cultivated in the United States. Registered non-GE plant producers would also need to provide the GPS coordinates of their crop fields using this system in order to receive the protections provided under 7 CFR part 340.

Further, the only regulated GE plants that would be permitted for commercial-scale cultivation in the United States would be those plants that have been granted international approval in the major export markets. This requirement would be instituted to reduce the potential for low level presence (LLP) of unapproved plants in shipments exported to other countries.

Tracking and reporting: GE plant developers would be required to maintain and provide to APHIS a list of regulated crop plants they offer for sale each year and verify whether these crops have been approved for import into major international export markets. Developers and producers of regulated GE plants would be required to track and record the planting locations and acreage of all regulated crop plants and submit that information to APHIS as requested. All registered producers of non-GE plants would likewise need to track, record, and

report the location and acreage of their crops on a voluntary national pinning map in order to receive protections under 7 CFR part 340.

Isolation distances: GE developers and producers would need to verify that all regulated GE plants maintained the isolation distances from non-GE plants specified in the permit. Permits would specify the isolation distance necessary to separate the GE and non-GE plants to achieve less than 0.1 percent cross pollination for seed production and 1 percent for grain production. Producers of regulated GE plants would share the responsibility for meeting the isolation distance with non-GE plant producers; producers of both non-GE and regulated GE plants would need to contribute equally to the isolation distances required for maintenance of registration and permit requirements, respectively. USDA organic standards require that organic farmers use certain preventative measures to minimize the risk of contamination, including maintaining buffer zones adequate to protect crops from chemical spray drift or cross-pollination (7 CFR Part 205, National Organic Program). Biotechnology developers would have responsibility for obtaining permits and ensuring isolation distances and volunteer plant management requirements were met. Similarly, non-GE plant producers would be required to maintain their registration with APHIS and adhere to registration requirements.

Volunteer plant management: Permits would require volunteer plant management plans be developed and implemented to prevent regulated GE plants from flowering in abandoned, fallow, and rotated fields. All land used for regulated GE plant production would have to be monitored pursuant to permit requirements to ensure that crops are harvested and volunteers are managed in abandoned, fallow, and rotated fields.

Compliance: Under this alternative, developers and growers of regulated GE plants could be held accountable for harm to non-GE producers if isolation distances and other permit

conditions are not followed. Non-GE plant producers who felt that isolation distances were not maintained could request an inspection by APHIS. If the APHIS inspection revealed that the isolation distance was in violation of permit requirements, the GE developer would be subject to penalties as described in the PPA (§ 7734). If required isolation distances were found to be maintained and all other permit conditions were followed, the GE developer would not be subject to penalties.

For the purposes of Alternative 3, GE plants that pose a noxious weed risk are termed plant health noxious weeds (PHNW). Those GE plants determined by APHIS to potentially cause economic harm not related to plant health to non-GE plant producers, their products, or agricultural commodity markets are termed mere presence noxious weeds (MPNW).

As with the proposed rule, the importation, interstate movement, and environmental release of all regulated GE organisms would be conducted solely under APHIS permit; the notification procedure and courtesy permits would be eliminated. Under this Alternative 3, permitting procedures and requirements for environmental releases would be the same as that described for the proposed rule for those organisms that posed plant pest and noxious weed risks as defined under the proposed rule. Those GE organisms deemed to present risks as MPNWs, including those previously deregulated, would have different permitting requirements aimed at promoting coexistence and minimizing incidents of unintended presence, where activities related to plant health risks such as cleaning equipment, disposition, or movement would not be necessary.

Requirements for the importation and movement of regulated organisms would be the same as those under the proposed rule. However, permits would not be required for the importation and interstate movements of GE organisms that presented MPNW risks.

Costs and Benefits of the Alternative: This alternative would assign liability on strictly economic terms for products that do not demonstrate plant health risks. It would provide some protection to organic and other non-GE plant growers against losses from the unintended presence of GE traits. It would also provide producers with protection against export market disruptions and associated losses that may occur when adoption of a GE trait occurs in the United States prior to its approval in an export market.

This alternative would affect biotech developers, firms that market GE seed, growers of GE and non-GE crops, and APHIS. Crops produced on approximately one-half of the arable land in the United States, 170 million acres, could be affected. Biotech developers would have increased tracking and monitoring responsibilities, and the collection and monitoring of planting data could be intrusive for affected GE plant producers. Biotech developers would also have greatly increased liability exposure. In cases where the permit conditions are not followed and a non-GE plant producer suffers a demonstrated loss, the biotech developer would be subject to penalties as described in the PPA (§ 7734). In addition, this alternative would delay the launch of GE plants until approvals have been granted in major export markets. Such delays in commercialization of a GE trait could substantially impact the returns to the biotech developer and the growers who adopt that trait (Phillips 2014). GE growers would be responsible for removing farmland from production or at least growing non-GE plants on a portion of the isolation buffer areas. This would decrease the profitability of those acres for GE adopters, and potentially decrease the adoption and planting of GE crops overall and increase consumer prices. To the extent that this alternative would increase buffer areas, the cost of providing those areas is a net loss to society regardless of who pays for them. Grass buffers are often not harvested, so farmers lose all of the value that could have been gained from growing crops on that land.

Organic farmers who grow conventional crops as buffers are able to sell the harvested buffer to the conventional market, but they lose the value of the organic premium for those acres. Farmers of GE crops who grow conventional crops as buffers are also able to sell the harvested buffer to the conventional market, but they similarly lose the benefits of the adoption of GE crops on those acres. All of the above factors may also reduce GE innovation and the associated benefits to biotech developers, GE crop growers, and consumers.

Organic and non-GE crop growers would also be impacted by this alternative. They would receive some protection against losses from the unintended presence of GE traits. However, in order to receive protection, organic and non-GE crop growers would need to record their crop locations, and take part in a certification program to establish authenticity. Certification of non-GE crop producers would be necessary to prevent non-legitimate interests from spuriously claiming non-GE status in order to impose requirements on neighboring GE producers. Some costs for non-GE crop producers may decline because GE adopters would absorb some of the cost of reducing the risk of unintended cross-pollination.

USDA would need to develop a national system to identify the location of non-GE plants, and a system to certify non-GE plant producers. USDA would also need to provide a large number of additional inspectors and devote increased resources for the testing of GE plants that may grow within the isolation buffer areas. APHIS would also need to provide a large number of additional inspectors and devote increased resources to the administration of compliance and response to complaints of noncompliance, such as with required crop isolation distances. These costs are expected to be significant considering APHIS inspections currently administer around 400,000 acres and this alternative would increase the scope of potentially permitted area to about 170 million acres.

APHIS has never regulated based on economic effects alone in the absence of any actual biological, chemical, or physical damage. This regulatory role would be inconsistent with the Agency mission and with current APHIS programs which are aimed at preventing the introduction and spread of plant pests and noxious weeds.

Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to evaluate the potential effects of their proposed and final rules on small businesses, small organizations and small governmental jurisdictions. This initial regulatory flexibility analysis describes expected impacts of this proposed rule on small entities, as required by section 603 of the Act.

Reasons Action is Being Considered

APHIS is proposing to amend 7 CFR part 340, which regulates the interstate movement, importation, and environmental release of GE organisms that may be plant pests or that there is reason to believe are plant pests. The regulations in 7 CFR part 340 were promulgated in 1987 under the authority of the Federal Plant Pest Act of 1957 and the Plant Quarantine Act of 1912. These acts, and others, were subsequently subsumed within the Plant Protection Act (PPA) of 2000. The proposed comprehensive revisions would be the first of this sort undertaken since enactment of the PPA and would bring 7 CFR part 340 in alignment with this Act. Advances in genetic engineering and oversight experience gained by APHIS underlie the decision to revise and update the regulations. The proposed changes would improve the regulatory process by providing greater transparency, flexibility, and efficiency.

Objectives of and Legal Basis for the Rule

The objective of this rule is to amend 7 CFR 340 to provide consistency with the PPA by incorporating the noxious weed authority provided by the PPA, and to improve efficiencies in

APHIS regulation of GE organisms. The proposed rule draws upon experience gained during 29 years of regulating GE organisms. The PPA authorizes the Secretary of Agriculture to implement programs and policies designed to prevent the introduction and spread of plant pests and diseases and noxious weeds.

Potentially Affected Small Entities

The proposed rule is expected to benefit a variety of small entities, directly and indirectly, including GE-related public and private research facilities, seed and crop producers, food processors, grain processors, and, and paper producers. Regulatory costs borne by biotech developers, some of whom are considered small, would decline. Permit preparation requirements would be reduced and petitions would be eliminated. Indirect benefits would include more timely international regulatory approvals, facilitation of small companies' ability to raise venture capital, and increased participation by the public sector in GE research. The latter effects can be expected to spur GE innovations, further benefiting small-entity producers of GE crops.

On the other hand, an increased rate of GE crop innovation may negatively affect growers of organic or other identity-preserved crops because of the increased risk of unintended presence of GE traits. Most of the growers of non-GE crops are small entities.

Entities affected by this proposed rule fall into various categories of the North American Industry Classification System (NAICS). For the purpose of this analysis and following the Small Business Administration (SBA) guidelines, potentially affected entities are classified within the following sectors: Agriculture, Forestry, Fishing and Hunting (Sector 11), Manufacturing (Sectors 31-33), Wholesale Trade (Sector 42), Retail Trade (Sectors 44 and 45), Transportation (Sectors 48 and 49), and Professional, Scientific and Technical Services (Sector 54). The small-entity definitions that follow are SBA standards.

For the Agriculture, Forestry, Fishing and Hunting sector, the subsectors of Crop Production, Animal Production, Forestry and Logging, and Support Activities for Agriculture and Forestry are potentially affected by this rule. The proposed rule may affect numerous establishments in the Crop Production category. Establishments in this category are considered small if annual sales are not more than $0.75 million. According to the 2012 Census of Agriculture, 92 percent of the farming businesses are considered small.[22] Potentially affected crop-producing industries, with their NAICS codes in parentheses, are as follows: Soybean Farming (111110); Oilseed Farming (except soybean) (111120); Dry Pea and Bean Farming (111130); Wheat Farming (111140); Corn Farming (111150); Rice Farming (111160); Oilseed and Grain Combination Farming (111191); All Other Grain Farming (111199); Potato Farming (111211); Other Vegetable (except potato) and Melon Farming (111219); Orange Groves (111310); Citrus (except orange) Groves (111320); Apple Orchards (111331); Grape Vineyards (111332); Strawberry Farming (111333); Berry (except Strawberry) Farming (111334); Tree Nut Farming (111335); Fruit and Tree Nut Combination Farming (111336); Other Noncitrus Fruit Farming (111337); Mushroom Production (111411); Other Food Crops Grown Under Cover (111419); Nursery and Tree Production (111421); Floriculture Production (111422); Tobacco Farming (111910); Cotton Farming (111920); Sugarcane Farming (111930); Hay Farming (111940); Sugar Beet Farming (111950); Peanut Farming (111960); and All other Miscellaneous Crop Farming (111970).

In terms of animal production, potentially affected entities include ones within the following industries: Beef Cattle Ranching and Farming (112111); Cattle Feedlots (112112);

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[22] U.S. 2012 Agriculture Census, Table 66: http://www.agcensus.usda.gov/Publications/2012/Full_Report/Volume_1,_Chapter_1_US/st99_1_066_066.pdf

Hog and Pig Farming (112210); Sheep Farming (112410); and Goat Farming (112420). Except for Cattle Feedlots, entities in all of these industries are considered small if annual sales are not more than $0.75 million. Cattle Feedlot establishments are considered small if annual sales are not more than $7.5 million. According to the 2012 Census of Agriculture, 80 percent of Cattle Feedlot businesses, 98 percent of Beef Cattle Ranching and Farming businesses, 65 percent of Hog and Pig Farming businesses, and 99 percent of Sheep and Goat farming businesses are small.[23]

For the Forestry and Logging subsector the potentially affected establishments are classified within Timber Tract Operations (113110); Forest Nursery and Gathering of Forest Products (113210); and Logging (113310). Establishments in the category of Timber Tract Operations and Forest Nursery and Gathering of Forest Products are considered small if annual sales are not more than $11 million and establishments in the category of Logging are considered small if the number of employees is not more than 500. However, neither the Census of Agriculture nor the Economic Census tracks revenue for establishments classified within Timber Tract Operations and Forest Nursery and Gathering of Forest Products and Logging.

In terms of Support Activities for Agriculture and Forestry, the potentially affected establishments are classified within Cotton Ginning (115111) and are considered small if annual sales are not more than $11 million; entities within Soil Preparation, Planting, and Cultivating (115112), Crop Harvesting (115113), and Postharvest Crop Activities (except cotton ginning) (115114) and are considered small if annual sales are not more than $27.5 million; and entities within Farm Management Services (115116), Support Activities for Animal Production

[23] U.S. 2012 Agriculture Census, Table 68: http://www.agcensus.usda.gov/Publications/2012/Full_Report/Volume_1,_Chapter_1_US/st99_1_068_068.pdf

(115210), and Support Activities for Forestry (NAICS 115310) are considered small if annual sales are not more than $7.5 million. However, neither the Census of Agriculture nor the Economic Census reports revenue for these establishments.

Entities that may be directly affected by the proposed rule in the Manufacturing Sector are classified within Ethyl Alcohol Manufacturing (325193); Pesticide and Other Agricultural Chemical Manufacturing (325320); Pharmaceutical Preparation Manufacturing (325412); and Medicinal and Botanical Manufacturing (325411). Establishments in the Ethyl Alcohol Manufacturing category are considered small if they employ not more than 1,000 persons and those in the category of Pesticide and Other Agricultural Chemical Manufacturing (NAICS 325320) are considered small if they employ not more than 500 persons. For both the Pharmaceutical Preparation Manufacturing (325412) and Medicinal and Botanical Manufacturing (325411) categories, establishments are considered small if they employ not more than 750 persons.

According to the 2012 Economic Census, there were 222 establishments in the Ethyl Alcohol Manufacturing (325193) and all employed fewer than 1,000 employees and are therefore considered small. For Pesticide and Other Agricultural Chemical Manufacturing (325320), only two of the 210 establishments employed more than 500 persons. The majority of entities classified within the Pharmaceutical Preparation Manufacturing (325412) and Medicinal and Botanical Manufacturing (325411) categories are small. Of the 1,165 entities in the former industry, 53 had more than 500 employees. For the latter industry, 11 of the 427 establishments employed more than 500 persons.

In terms of Wholesale Trade, entities that would be potentially affected may be found in the following categories: Fresh Fruit and Vegetable Merchant Wholesalers (424480); Other

Grocery and Related Products Merchant Wholesalers (424490); Grain and Field Bean Merchant Wholesalers (424510); Other Farm Product Raw Material Merchant Wholesalers (424590); Farm Supplies and Merchant Wholesalers (424910); and Flower, Nursery Stock, and Florists' Supplies Merchant Wholesalers (424930). Establishments in the above categories are considered small if they employ not more than 100 persons. According to the 2007 Economic Census, 95 percent of the establishments in this category employed fewer than 100 people and are considered small.

Retail establishments that may be affected fall within various NAICS categories. Establishments classified within Nursery and Garden Centers (444220) are considered small if annual sales are not more than $11 million. According to the 2007 Economic Census, there were 15,895 establishments of which 13,748 operated the entire year. Of the establishments that operated the entire year, 95 percent have sales of less than $10 million. Supermarkets and Other Grocery Stores (445110) are considered small if annual sales are not more than $32.5 million. Of the 64,881 establishments in 2007, 55,926 operated the entire year. Of the establishments that operated the entire year, 90 percent had annual sales of less than $25 million. Given this information, we can assume that the majority of the establishments in this industry are small. For businesses classified within Fruit and Vegetable Markets (445230), 2,157 of the 2,938 establishments operated the entire year and 94 percent had sales less than the SBA threshold of $7.5 million, according to the 2007 Economic Census. All Other Specialty Food Stores (445299) are small if annual sales are not more than $7.5 million. In 2007, 3,688 of the 5,504 establishments operated the entire year. Of the establishments that operated the entire year, 99 percent had annual sales of less than $5 million and are considered small. Food (Health) Supplement Stores (446191) are considered small if annual sales are not more than $15 million. Of the 8,999 total establishments in 2007, 7,897 operated the entire year and 99 percent had sales

of less than $10 million. Entities classified within Warehouse Clubs and Superstores (452910) are considered small if annual sales are not more than $29.5 million. In 2007, there were 4,260 establishments of which 4,196 operated the entire year. Of those that operated the entire year, 4,031 had receipts greater than $25 million. The Census did not report establishments that had annual sales greater than $29.5 million. Florists (453110) are considered small if annual sales are not more than $7.5 million. The 2007 Economic Census reports that there were 19,822 establishments in this category of which 16,736 operated the entire year. Of the establishments that operated the entire year, 32 had sales greater than $5 million. We can therefore assume that the majority of businesses in this category are small.

In terms of Warehousing and Storage, the potentially affected entities are in the category Farm Product Warehousing and Storage (493130). Establishments in this category are considered small if annual sales are not more than $27.5 million. According to the 2007 Economic Census, there were 600 establishments of which 567 operated the entire year. Of the establishments that operated the entire year, 28 had annual revenue great than $25 million. Ninety-five percent of the establishments that operated the entire year are considered small.[24]

In terms of Professional, Scientific and Technical Services, establishments in the category of Research and Development in Biotechnology (541711) may be affected. Establishments in this category are considered small if they employ not more than 500 persons. The 2012 Economic Census in not complete but according to 2007 Economic Census, there were

[24] 2007 Economic Census, American Factfinder: http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_48SSSZ4&prodType=table

2,483 establishments of which 2,167 operated the entire year. Of the establishments that operated the entire year 1,977 or 90 percent had fewer than 100 employees and are considered small.

Although data are not available on the business sizes for all potentially affected establishments, based on the foregoing information we can assume that the majority of the entities that may be affected by the proposed rule are small.

Projected Reporting, Recordkeeping, and Other Compliance Requirements

Reporting and recordkeeping requirements associated with the proposed rule are discussed in the rule under the heading "Paperwork Reduction Act." The public reporting burden for this collection of information is estimated to average .828 hours per response. The estimated total annual burden on respondents (developers of organisms regulated under 7 CFR part 340; businesses and individuals associated with such organisms; Tribal governments) is 4,174 hours. This total burden assumes 5,035 responses per year, based on an estimated 311 respondents and an estimated 16 responses per respondent. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Duplication, Overlap, or Conflict with Existing Rules and Regulations

APHIS has not identified any duplication, overlap, or conflict of the proposed rule with other Federal rules. Most GE organisms are subject to permitting requirements under the current regulations, while under the proposed rule most GE organisms would not be subjected to permitting requirements. The proposed rule would therefore represent a reduction in APHIS' regulation of certain GE organisms within the 1986 Coordinated Framework for Regulation of Biotechnology.

Alternatives to minimize Significant Economic Impacts of the Rule

APHIS does not expect the proposed rule to have a significant economic impact on a substantial number of small entities. We have prepared this initial regulatory flexibility analysis based on our review of currently available information. In the absence of apparent significant economic impacts, we have not identified alternatives that would minimize such impacts.

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Appendix Tables

The tables in this appendix show the derivation of APHIS staffing expenditures expected to be affected by the proposed rule, in regulating GE organisms. The costs are based on the time required per task, multiplied by the number of employees and their grade-level salaries in 2015. Total costs include benefits and overhead of 31.7 percent. The General Schedule salary table is included as Appendix Table 10.

Appendix Table 1: Calculation of current costs associated with conducting NEPA analyses, 2015 dollars

Activity	Time per Task (hours)	Number of People	GS Level	Number of Times per Year	Total Cost per Year (dollars)
Extension FONSI (Finding of No Significant Impact)	80	2	12 to 14	2	15,902
Extension Environmental Assessment (EA) and FONSI	180	2	13 and 14	1	19,368
Final EA and FONSI – path I	360	3	12 to 14	2	107,338
Draft EA – path II	600	4	12 to 14	4	477,056
Final EA, RTC, and FONSI – path II	144	4	13 and 14	6	185,933
Notice of Intent (NOI)	80	2	12 to 14	1	7,951
Draft Environmental Impact Statement	2,080	8	12 to 14	1	826,897
RTC for an EIS	160	3	12 to 14	1	23,853
Final EIS	2,080	3	13 and 14	1	335,712
Record of Decision	80	1	12 to 14	1	3,975
Regulatory workplan, 4-point memo, and OGC waiver for initial FR publication	8	1	13 and 14	10	4,304
Regulatory workplan, 4-point memo, and OGC waiver for subsequent FR publications	8	1	13 and 14	6	2,582
Total without benefits and overhead					**2,010,871**
Total Cost per year with Benefits and Overhead					**2,648,317**

Notes: Lower-bound costs under the proposed rule assume one-half of the current workload. Upper-bound costs under the proposed rule assume twice the current workload.

Appendix Table 2: Calculation of expected costs under the proposed rule associated with conducting weed risk assessments (WRA), 2015 dollars

WRA (Lower Bound Estimates)	Time (hours)	Number of people	GS level	Cost GS 13 per Average Time	Cost GS 14 per Average Time	
Draft and clear WRA	2,080	4	13	102,586		410,342
Review WRA	2,080	1	14		121,222	121,222
Total without benefits and overhead						**531,565**
Total Cost Per Year with Benefits and Overhead						**700,071**
WRA (Upper Bound Estimates)						
Draft and clear WRA	2,080	7	13	102,586		718,099
Review	2,080	2	14		121,222	242,445
Total without benefits and overhead						**960,544**
Total Cost Per Year with Benefits and Overhead						**1,265,036**

Appendix Table 3: Calculation of current costs associated with compliance and inspections, 2015 dollars

Based on 800 Inspections	**Time (hours)**	**Number of People**	**GS Level**	**Total Cost per 800**
Collect information	630	2	8 and 11	38,115
Select sites	72	2	14	8,392
Prepare Worksheet	107	1	11	3,702
Review and prepare worksheet	67	1	12 to 13	3,042
Writing inspection reports	1,974	1	11 to 12	75,091
Writing inspection reports	1,750	1	11 to 12	66,570
Review inspection reports	1,400	1	12 to 13	63,560
Subtotal without benefits and overhead				**258,472**
Subtotal with benefits and overhead				**340,408**
	Per year			
Based on 100 incidents per year	300	1	13	14,796
Quality Assurance Quality Control Response	6	1	14	350
Warning Letters	4	1	13	197
Warning Letters	1	1	14	58
Total Cost Per Year with Benefits and Overhead				**360,691**

Note: Lower-bound costs under the proposed rule assume 800 inspections per year, the same as at present. Upper-bound costs under the proposed rule assume 1,500 inspections per year, plus a time increase of 50 percent.

Appendix Table 4: Calculation of current costs associated with "Am I Regulated" (AIR) process, 2015 dollars

Activity	Time (hours)	Number of people	GS level	Times per year	Total Cost per Year
Drafting response	6	1	GS12 to 14	7	2,087
Reviewing response					
Staff meetings	2	10	GS9 to 14	1	860
Program Directors meeting	2	7	GS15 to SES,SL	1	1,012
Office of Deputy Administrator	2	2	GS15 to SES,SL	5	1,446
Total without benefits and overhead					**5,406**
Total Cost Per Year with Benefits and Overhead					**7,120**

Note: SES and SL salaries are calculated at a GS 15 step 10 level.

Appendix Table 5: Calculation of current costs associated with notifications, 2015 dollars

Activity	Time (hours)	Average Time (hours)	Number of people	GS level	Times per year	Total Cost per Year
1. Notification - Import						
a. Total time spent by Program Specialist	2	2	1	12	97	8,047
b. Total time spent by Biotech	1.25	1.25	1	12 - 14	97	6,025
1. Notification -movement						
a. Total time spent by Program Specialist	1.5	1.5	1	12	325	20,222
b. Total time spent by Biotech	1.25	1.25	1	12 - 14	325	20,188
2. Notification – Release + Movement/Release						
a. Total time spent by Program Specialist	2	2	1	12	334	33,195
b. Total time spent by Biotech	4 (2 - 8)	4	1	12 - 14	334	66,390
Total without benefits and overhead						**154,067**
Total Cost Per Year with Benefits and Overhead						**202,907**

Appendix Table 6: Calculation of current costs associated with permits, 2015 dollars

Activity	Time (hours)	Average Time (hours)	Number of people	GS level	Times per year	Total Cost per Year
1. Permits – Import						
a. Total time spent by Program Specialist	2	2	1	12	39	3,235
b. Total time spent by Biotech	(1 to 10)	2	1	14-Dec	39	3,876
c. Branch Chief	0.25	0.25	1	14	39	568
1. Permits - Movement						
a. Total time spent by Program Specialist	1.5	1.5	1	12	104	6,470
b. Total time spent by Biotech	(1 to 10)	2	1	14-Dec	104	10,336
c. Branch Chief	0.25	0.25	1	14	104	1,515
2. Permits – Release + Movement/Release						
a. Total time spent by Program Specialist	2	2	1	12	190	18,883
b. Total time spent by Biotech	(5 - 42)	12	1	14-Dec	190	113,300
c. Branch Chief	0.5 to 2	1	1	14	190	11,073
EA for Permits	160	160	1	14-Dec	1.5	11,926
Total without benefits and overhead						**181,186**
Total Cost Per Year with Benefits						**238,622**

Note: Lower-bound costs under the proposed rule assume 12 import, 88 interstate movement, and 100 movement and environmental release permits. Upper-bound costs under the proposed rule assume 24 import, 176 interstate movement, and 200 movement and environmental release permits.

Appendix Table 7: Calculation of current costs associated with petitions, 2015 dollars

Activity	Time (hours)	Number of people	GS level	Times per year	Total Cost per Year (dollars)
1. Petition Completeness review					
a. Administrative processing of incoming petition	2	2	5 - 13	6(DCO Step)	782
b. Team assigned, reviews petition, and preps deficiency letter	363	5	12 - 15	6	639,635
c. Review and send deficiency letter	24	4	12 - 14	6	28,623
d. Administrative processing of deficiency letter response	2	2	5 - 13	6(DCO Step)	870
e. Review of response, draft letter of completion	37	4	12 - 14	6	44,128
f. Review, clear and send letter of completion	3	2	13-14	6	1,937
g. Publish petition	10	2	12 - 14	6	5,963
2. Plant Pest Risk Assessment (PPRA)					
a. Draft and clear PPRA	360	2	12 - 14	6	214,675
3. Environmental Assessment (EA)					
Final EA and FONSI – path 1	360	3	12-14	3	161,006
Draft EA – path I2	600	4	12-14	3	357,792
Final EA, RTC, and FONSI – path 2	144	4	12-14	3	85,870
4. Publish EA (Path 1)					
i. Develop and clear determination	7	3	15 - SES	3	4,555
ii. Approval of Final EA and supporting documentation	21	3	15 - SES	3	13,665
iii. Regulatory workplan for EA (draft and clear)	15	4	14 - SES	3	12,173
5. Publish EA (Path 2)					
i. Approval of EA for publication	20	3	15 - SES	3	13,014
ii. Regulatory workplan for EA (draft and clear)	15	4	14 - SES	3	11,349
viii. Develop and clear Determination	4	3	15 - SES	3	2,603
ix. Approval of Final EA and supporting documentation	24	3	15 - SES	3	15,617
6. All docket related items (workplans, 4 point memo, Office of General Counsel waiver, Federal Register)	8	1	12-14	8	3,180
Total without benefits and overhead					1,617,438
Total Cost Per Year with Benefits and Overhead					**2,130,166**

Note: Paths 1 and 2 are alternative pathways that a petition can take. In Path 1, we publish a final EA in the Federal Register, whereas in path 2 we first publish a draft EA for public comment and after revisions in response to comments a final EA.

Appendix Table 8: Other Developer Costs associated with the part 340 Regulations, 2015 dollars

Section of the Regulations	Number of Respondents	Hours Per Year	Equivalent GS level (1)	Cost ($1,000)
340.3 – Procedure for Permits (new community of permittees only)	50	500	12	27
340.4 – Regulatory Status Evaluation	300	3000	13-14	198
340.4 – Reconsider Regulatory Status Evaluation	10	200	14-SES	16
340.3 – State and Tribal Review	20	200	14	0.08
340.3- Record Retention	1	1	13-14	32
340.3 - Marking/Labeling	150	15	12	0.82
340.3 Reports on Characteristics	12	6	12	0.34
340.3 - Notification of Certain Occurrences	1	1	12	0.05
340.3 - Appeal of Withdrawal of Permit	1	1	12	0.06
Total Record Keeping Costs (2)				**275**
Costs of Rule Familiarization (3)	1,100	8	14	**576**
Total Additional Costs				**851**

(1) GS level salaries are used as a proxy for salaries the managers in responding entities to estimate the cost of those activities.

(2) Recordkeeping cost tabulations are based on the information collection categories from the paperwork burden section of the rule.

(3) This is a one-time cost. There have been about 1,100 unique entities who have applied for permits or notifications under part 340.

Appendix Table 9: Other APHIS' Costs Associated with the Rule, 2015 dollars

Activity	Time (hours)	GS Level	Cost ($1,000)
Outreach (1)			
Develop guidance documents	160	14	12
	40	15	4
Develop and deliver 3 public webinars	48	12	4
	48	13	7
	48	14	6
	24	15	5
Total Outreach Activities			39
Training	640	14	49
Adjusting the permit system (1)			0
Total Additional Costs			**88**

(1) Requests for regulatory status and response letters under the proposed rule could be handled in a manner similar to the current 'Am I Regulated' process outside the electronic permitting system without new costs.

Appendix Table 10: General Schedule (GS) Salary Table, 2015 dollars, Washington, DC area

GS Level	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7	Step 8	Step 9	Step 10
1	10.81	11.17	11.53	11.89	12.25	12.46	12.81	13.17	13.19	13.52
2	12.15	12.44	12.85	13.19	13.33	13.73	14.12	14.51	14.9	15.3
3	13.26	13.7	14.15	14.59	15.03	15.47	15.91	16.36	16.8	17.24
4	14.89	15.38	15.88	16.38	16.87	17.37	17.87	18.36	18.86	19.35
5	16.66	17.21	17.77	18.32	18.88	19.43	19.99	20.54	21.1	21.65
6	18.57	19.18	19.8	20.42	21.04	21.66	22.28	22.9	23.52	24.14
7	20.63	21.32	22.01	22.69	23.38	24.07	24.76	25.44	26.13	26.82
8	22.85	23.61	24.37	25.13	25.9	26.66	27.42	28.18	28.94	29.7
9	25.24	26.08	26.92	27.76	28.6	29.44	30.28	31.12	31.96	32.81
10	27.79	28.72	29.64	30.57	31.5	32.42	33.35	34.27	35.2	36.13
11	30.53	31.55	32.57	33.59	34.6	35.62	36.64	37.66	38.68	39.69
12	36.6	37.82	39.04	40.26	41.48	42.7	43.92	45.14	46.36	47.58
13	43.52	44.97	46.42	47.87	49.32	50.77	52.22	53.67	55.12	56.57
14	51.43	53.14	54.85	56.57	58.28	60	61.71	63.43	65.14	66.85
15	60.49	62.51	64.52	66.54	68.56	70.57	72.59	74.61	76.04	76.04

Source: Office of Personnel Management (OPM): https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/15Tables/html/DCB_h.aspx